Draft proposal for a European Partnership under Horizon Europe Pandemic Preparedness

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TABLE OF CONTENTS

ist of Acronyms	3
. GENERAL INFORMATION	5
1.1. Draft title of the partnership	5
1.2. Lead entity (main contact)	
1.3. Commission services (main contact)	
1.4. Summary (max 500 characters)	ε
CONTEXT, OBJECTIVE, EXPECTED IMPACTS	7
2.1 Context and problem definition	
2.1.1 Context of the partnership	
2.1.2 Action is needed now	
2.1.3 General problems and challenges	
2.1.4 Underlying drivers of impact	
2.1.5 Addressing market failures and bottlenecks	
2.1.6 Serving public and private interest	
2.1.7 Building on experience of prior R&I EU-funded initiatives	
2.1.8 Key R&I challenges and gaps	
2.2 Common vision, mission, objectives and expected impacts	
2.2.1 Vision, mission and objectives of the Partnership	
2.2.3 Links and collaboration opportunities with other Partnerships and European Union programs	
2.2.4 Estimated R&I investments necessary to achieve the specific objectives	
2.2.5 How the proposed Partnership is expected to trigger relevant transformational changes	
2.2.6 Exit-strategy and measures for phasing-out from the Framework Programme funding	
2.3 Necessity for a European Partnership	
2.3.1 How the Partnership addresses the objectives of Horizon Europe and common political price	
the EU and its Member States	
2.3.2 How the partnership will establish a meaningful collaboration with Member States /As	
Countries and relevant national/regional authorities	
2.4. Partner composition and target groups	
2.4.1 How will the Partnership build upon, strengthen and/or expand collaboration networks and in	
that are currently existing at the EU level, beyond currently existing Partnerships	
2.4.2 Justify the type and composition of partners	31
2.4.3 Describe the envisaged target groups / stakeholder community	32
3. PLANNED IMPLEMENTATION	33
3.1. Activities	
3.1.1 Achieving the Partnership Objectives	
3.1.2 Mechanisms which will ensure the complementarity	
3.1.3 Synergies with national (sectorial) policies, programmes and activities	
3.2. Resources	
3.3. Governance	37
3.3.1 Governance and management of the Partnership	
3.3.2 Coherence and synergies with the EU research and innovation landscape	
3.3.3 The role of European Commission in the Partnership	
3.4. Openness and transparency	39
3.4.1 Partnership transparency and openness	
3.4.2 Non-discriminatory access to the Partnership and Recruitment	
3.4.3 Process for establishing annual work programmes	41
Annex I	42
Annex II.	

List of Acronyms

AIDS Acquired immunodeficiency syndrome

AMR Antimicrobial resistance

BBMRI ERIC European Research Infrastructure for Biobanking and Biomolecular Resources

BY COVID BeYond COVID

COVID-19 Coronavirus Disease 2019

CSA Coordination and Support Action

EATRIS European Infrastructure for Translational medicine

EC European Commission

ECDC European Centre for Disease Prevention and Control

ECRIN ERIC European Clinical Research Infrastructure Network

EDCTP European and Developing Countries Clinical Trials Partnership

EID Emerging Infectious Disease

ELIXIR Life-Science Infrastructure for Biological Information

EMA European Medicines Agency

ERA European Research and Innovation Area

ERA4Health Fostering a European Research Area for Health Research

ESCAPE European Science Cluster of Astronomy & Particle physics ESFRI research

infrastructures

ERDF European Regional Development Fund

ESF+ European Social Fund Plus

EU European Union

GLoPID-R Global Research Collaboration for Infectious Disease Preparedness

HERA Health Emergency Preparedness and Response Authority

HIV human immunodeficiency virus

IHI Innovative Health Initiative

ISIDORE Integrated Services for Infectious Disease Outbreak Research

MERS Middle East Respiratory Syndrome

Mpx Monkeypox

MS/AC Member States or Associated Countries

NPI Non-pharmaceutical intervention

PAHW European Partnership on Animal Health & Welfare

PANDASIA Pandemic Literacy and Viral Zoonotic Spillover Risk at the Frontline of Disease

Emergence in Southeast Asia to Improve Pandemic Preparedness

PCR-4-ALL Polymerase chain reaction for all

PHSM Public Health and Social Measures

PS Partnership

RRF Recovery and Resilience Facility

R & I Research and Innovation

SARS Severe acute respiratory syndrome

SARS-CoV-2 Severe acute respiratory syndrome coronavirus 2

SDG Strategic Development Goal

SRIA Strategic research and innovation agenda

TSI Technical Support Instrument

WHO World Health Organisation

1. General information

1.1. Draft title of the partnership

European Partnership for pandemic preparedness

Prepared by the CSA "Building a European strategic ResEArch and Innovation Area in Direct synergy with EU and international initiatives for pandemic preparedness" BE READY

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1.4. Summary (max 500 characters)

In light of the teaching of the COVID-19 pandemic and the increasing threat of emerging infectious diseases, the European Partnership on Pandemic Preparedness aims to enhance the European Union's research preparedness for emerging infectious health threats and reduce the burden of infectious diseases. Action is needed now to address the critical gaps in pandemic preparedness research and response, ensuring Europe is better equipped to tackle future health emergencies. Comprising four pillars, the partnership seeks to (i) align research efforts on pandemic preparedness, (ii) boost funding for innovative research, (iii) support research ecosystem readiness, and (iv) foster research and innovation skills. Central to its vision is the development of a Strategic Research and Innovation Agenda (SRIA) to guide common objectives and address gaps in pandemic preparedness research. By aligning stakeholders towards common goals, including policy-makers, research funders, and the scientific community, the partnership aims to enhance collaboration and coordination across national and international levels.

Through joint transnational research calls and other funding activities, the partnership will support excellence in basic, pre-clinical, clinical, and public health research. It will also bolster EU-wide infrastructures and adaptive trials to enable timely and coordinated responses during health emergencies. Additionally, the partnership will focus on capacity building, knowledge exchange, societal engagement, and the facilitation of data sharing to foster research and innovation skills essential for effective pandemic preparedness.

To ensure complementarity and coherence with other research initiatives, the partnership will establish governance structures for transparent decision-making and effective coordination. A Governing Board, Executive Board, and Partnership Management Team will oversee strategy implementation, operational management, and day-to-day activities. Advisory structures, including External Advisory and Clinical Research Advisory Boards, will provide expertise and guidance on scientific and operational matters. Importantly, the Board of Funders will oversee funding activities, ensuring alignment with the SRIA and strategic priorities.

Synergies with national and European policies, programmes, and activities will be pursued through cooperation frameworks and regular meetings, fostering interpersonal knowledge and trust among stakeholders across Europe. The partnership will serve as a knowledge hub, mapping relevant stakeholders, policies, and activities to support research on emerging infectious diseases and public health measures. By leveraging existing national and EU-level infrastructures, the partnership aims to strengthen the EU's role as a globally recognized actor in pandemic preparedness research and response.

The partnership is firmly anchored within the objectives of Horizon Europe and will work hand in hand with the European Commission, particularly DG RTD and HERA. The Commission will be represented in governance bodies, facilitating close alignment with EU objectives and ensuring transparency and openness throughout the partnership's duration.

In summary, the European Partnership on Pandemic Preparedness seeks to foster a collaborative and coordinated approach to research and innovation, guided by a common vision outlined in the Strategic Research and Innovation Agenda. Through its activities and governance structures, the partnership aims to establish a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases and that can respond to them swiftly and efficiently.

2. Context, objective, expected impacts

2.1 Context and problem definition

In the last century the world has witnessed several epidemics/pandemics. Since the early 1900s, there have been at least eleven serious viral outbreaks, caused by emerging pathogens. These pathogens span a number of five virus families¹² against which there were and are still insufficient countermeasures available (at least not in the region of the outbreak). Examples are influenza, Monkeypox virus, Ebola and finally the recent COVID-19 pandemic. The COVID-19 pandemic uncovered the challenges that European health care systems face in detecting, combatting and managing outbreaks of infectious diseases in a coordinated manner. It also illustrated the global lack of preparedness, inadequate availability of medical countermeasures, such as vaccines, therapeutics and diagnostics and lack of knowledge on how to encourage prosocial behaviour. Further, it showed how unilateral research initiatives may lead to a fragmented research landscape. At the same time, the relentless work of the research community that has led to availability of several COVID-19 vaccines in record time provides evidence of the critical importance of collaborative research and innovation (R&I) to respond rapidly to emerging health threats, as well as of the strategic value of public-private partnerships. As devastating as the COVID-19 pandemic has been, there is a reasonable probability that another serious pandemic will occur in the future. Therefore, European-level investments in pandemic preparedness are crucial and should be made promptly. Looking forward, it's vital to apply lessons learned and enhance collaborative efforts for pandemic preparedness to effectively mitigate, prepare, respond, and recover.

2.1.1 Context of the partnership

The creation of this partnership with a focus on pandemic preparedness provides a unique strategic opportunity for coordinated, relevant, timely and evidence-based research and innovation. The COVID-19 pandemic highlighted how fast things can change for the worse or the better. Europe can only be prepared adequately to act in timely fashion for a next epidemic/pandemic, when we have a functioning partnership that establishes a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases, that can respond to them swiftly and efficiently, and that is fully integrated in the wider European institutional Health Security framework. No single organisation or existing association alone can achieve the required level of coherence and defragmentation across Europe, necessary to maximise uptake and impact. This requires a collaborative Partnership.

Collaboration between Member States and various stakeholders is essential for fostering connectivity among communities and shaping policies and strategies for both public and private investments. Such a partnership plays a crucial role in promoting a targeted approach to research, innovation, an everwarm clinical trial research network, and deployment, leveraging European strengths. Additionally, this collaborative effort should extend its engagement to work in tandem with other global and regional partnerships. For a comprehensive but not-exhaustive list of partnerships, please refer to paragraph 2.2.3.

¹ https://doi.org/10.3389/fmicb.2020.631736

² https://doi.org/10.1016/S1473-3099(20)30484-9

2.1.2 Action is needed now

Establishing a collaborative partnership is imperative to supplement existing collaborations and initiatives, amplifying their impact and investments across various levels while effectively capitalizing on current and future opportunities. Given the existing opportunities and the momentum available, it is imperative to act now, especially as we continue to grapple with the aftermath of the COVID-19 pandemic in a modified context.

As described by the *Lancet* Commission on lessons learned for the future from the COVID-19 pandemic³:

"Coordination among governments was inadequate on policies to contain the pandemic, including travel protocols to slow the global transmission of the virus, testing strategies, public health and social measures, commodity supply chains, data standards and reporting systems, and advice to the public, despite the very high interdependence among countries."

Taking proactive measures now to establish this partnership will not only draw from the insights gained during the COVID-19 pandemic but also strengthen collaboration and coordination among Member States. The partnership will find its position in the existing European pandemic preparedness ecosystem by synergizing and aligning with existing relevant initiatives. Moreover, it will establish coherence and connections in areas related to pandemic preparedness, including Health and Care Systems R&I, Natural Disaster Risk Reduction, Antimicrobial Resistance, Climate Change.

This partnership is instrumental in shaping Europe's trajectory towards pandemic preparedness, assuming an important role in developing a holistic framework.

2.1.3 General problems and challenges

Europe, being a diverse community, faces various challenges, notably highlighted during the COVID-19 pandemic. Member States exhibited diverse approaches, emphasizing the fragmented research landscape with numerous actors at different levels (national, regional, local). The absence of clearly delineated procedures, in conjunction with an "infodemic"⁴, an overabundance information—encompassing both mis- and disinformation — exacerbates the complexities in handling cross-border issues for Member States.

Polarized public opinions and science skepticism can hinder the execution of coordinated efforts to counter health threats, which leads to non-compliance and a reduction in vaccination rates. The lack of cooperation and the erosion of public confidence in research, as well as the distrust in public authorities may have long-term effects that make it more difficult to effectively respond to future health emergencies⁵.

The Lancet commission paper highlighted several research and innovation challenges during the COVID-19 pandemic, including the lack of timely notification of the initial outbreak of COVID-19, knowledge gaps in understanding the airborne exposure pathway of SARS-CoV-2, the virus that causes COVID-19, and a lack of coordination among countries in implementing suppression strategies. Additionally, governments faced issues in examining evidence and adopt best practices for controlling

8

³ The Lancet Commission on the lessons learned for the future from the COVID-19 pandemic

⁴ World Health Organization. (2021). WHO competency framework: building a response workforce to manage infodemics. World Health Organization. (https://iris.who.int/handle/10665/345207 accessed 20 March 2024).

⁵ DOI: 10.1126/sciadv.abd4563

the pandemic, managing economic and social spillovers from other countries, ensuring adequate global supplies and equitable distribution of key commodities (e.g. personal protective equipment, diagnostics, medicines, medical devices and vaccines), obtaining timely, accurate and systematic data on various aspects of the pandemic (e.g. infections, deaths, viral variants, health system responses and indirect health consequences). Enforcement of biosafety regulations and combating systemic disinformation were also identified as areas requiring improvement.

The clinical research response, for example, starkly revealed the repercussions of a fragmented Union. In the EU, an unprecedented number of national academic clinical trials were initiated to expedite COVID-19 treatment and prevention. However, due to the absence of coordination across Member States, the result was a disorderly landscape marked by numerous underpowered trials unable to yield meaningful results, along with duplicated research activities.

Evidence should drive policy, and to ensure robust evidence generation in the EU, research should be more coordinated and less fragmented. The existence of shared and robust scientific evidence facilitates the effective coordination of public health measures. Research plays a pivotal role pandemic preparedness, necessitating a robust plan for research readiness in the EU. This involves establishing a basic research portfolio and clinical research preparedness, both in between and during pandemics.

To achieve this, a consolidated strategic research and innovation agenda (SRIA) and framework focused on pandemic preparedness are essential in the EU and beyond. The SRIA, serving as the basis for research and innovation priorities and activities, will be collectively agreed upon by the partnership members.

The SRIA should encompass not only fundamental, technical, epidemiological, and clinical aspects but also economic and social determinants such as poverty or inequality related to access to health services. Additionally, ethical considerations must be taken into account to assess the impact of measures on virus transmission versus their impact on society. Legal aspects should also be considered to ensure data sharing necessary for combating the epidemic while safeguarding privacy. Research on these topics is vital for pandemic preparedness.

Moreover, there is a lack of a solid evidence base and practical mechanisms explaining why certain innovative solutions struggle to transfer to other countries despite adding value in their countries of origin. Therefore, sharing experiences and information on effective and sustainable innovations in pandemic preparedness across biomedical, social, and technical sciences, as well as at organizational and service levels, can assist Member States in translating these solutions to their own national, regional, or local levels.

Cross-border learning from various health and research sectors is crucial for pandemic preparedness research. A comprehensive European partnership on pandemic preparedness will provide an appealing and logical platform for initiating international collaboration on research and innovation and for effective (inter)national dissemination of results.

2.1.4 Underlying drivers of impact

In the history of mankind change has always been factor in the evolution of our civilizations. Such is the case in the current world wherein we live. These changes -be it natural or anthropogenic- bring about several challenges to our society and way of living. Over the last decades major changes such as globalization and climate change, demographic change⁶, technological development, environmental factors and different political and societal landscape/structures have become more visible on the European continent and each in its own right influences' pandemic preparedness.

Global interconnectedness

The increased global mobility has granted us the freedom to explore various parts of the world. Within Europe, the ability to travel freely in the Schengen area has not only allowed citizens to discover different regions but has also opened up financial opportunities for work and travel across European countries. However, this global interconnectedness has contributed to the uncontrolled propagation of emerging infectious diseases and its impact on the citizens' health over the world and notably in Europe.

Furthermore, this heightened interconnectedness has underscored the importance of fostering scientific collaboration with countries facing a high risk of disease emergence. The lessons learned from the COVID-19 pandemic, as well as previous epidemics and pandemics like Monkeypox (mpox), should guide efforts to enhance early warning and surveillance systems within Europe. The partnership can contribute significantly by supporting research aimed at improving these warning and surveillance systems. Additionally, existing structures like Health Emergency Preparedness and Response Authority (HERA) can play a crucial role in implementing these enhancements.

Demographic changes

The aging population in Europe poses various challenges, including shifts in population composition and societal development. This demographic change introduces new challenges and heightened demands, impacting not only the healthcare system but also the overall workforce. The increase in life expectancy and the prevalence of long-term chronic diseases are significant drivers that must be addressed as integral components of pandemic preparedness. Furthermore, these challenges necessitate a coordinated approach in conjunction with the healthcare systems of Member States.

<u>Technological development</u>

Technological development and innovation are crucial drivers that emphasize the necessity for implementation research in advancing the field of pandemic preparedness. There is a growing need for a proactive and effective approach in prevention strategies. While technological advancements and digitalization provide opportunities, overcoming hurdles related to societal issues, technology acceptance, and public outreach is essential for successful implementation. Addressing these complex questions is imperative to develop a high-quality, robust, and effective pandemic preparedness framework.

Climate change

Climate change and environmental shifts impact Member States disparately. The 2021 report from the "Lancet Countdown on health and climate: code red for healthy future" highlights the escalating health risks attributed to changing environmental conditions. These changes increase the suitability for the transmission of various water-borne, air-borne, food-borne, and vector-borne pathogens. Despite socio-economic development and advancements in public health interventions and medicine

⁶ https://ec.europa.eu/futurium/en/system/files/ged/eprs-briefing-633160-demographic-trends-euregions-final.pdf

⁷ https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01787-6/fulltext

reducing the global burden of infectious diseases, climate change has the potential to (re)introduce or undermine efforts to eradicate pathogens with pandemic potential.

Beyond the risk of (re)emerging infectious diseases, climate change induces extreme weather conditions and seasonal temperature variations. The summer of 2022 marked the hottest on record for Europe⁸, contributing to 2022 being the second warmest year on record for the continent. Consequently, reports indicate a progressive increase⁹ in deaths due to extreme weather conditions. The partnership should leverage synergies across policy areas in alignment with the European Green Deal¹⁰, addressing these challenges for the benefit of the European Union and its citizens.

Intensive husbandry and agriculture and illegal wildlife trade.

Intensive husbandry and agriculture have expanded, negatively impacting natural ecosystems by causing biodiversity loss and substantial alterations to the ecological balance. This expansion has also led to heightened contact between wildlife and human populations. Simultaneously, the illicit wildlife trade contributes to the translocation of animal species from remote to densely populated areas. Collectively, these factors elevate the risk of pandemics by increasing the likelihood of zoonotic transmission¹¹.

2.1.5 Addressing market failures and bottlenecks

Despite its aspirations and objectives, the presented partnership cannot offer solutions to all the identified problems and bottlenecks, as some issues extend beyond its scope and pertain to societal or political concerns. However, the partnership can strive to generate new scientific evidence in interconnected areas, aiming to influence positive change.

This partnership faces different bottlenecks for many innovative solutions and the translation of research results of pandemic preparedness to different Member States.

- 1) Suboptimal scientific evidence that could be used across European countries on innovation's effectiveness and efficiency.
- 2) Lack of readiness of adaptive trials, cohorts, and shared protocols in order to test the candidate countermeasures when a crisis arises.
- 3) Limited understanding regarding:
 - a. Factors that contribute to the successful implementation of innovation in research on development of medical countermeasures, services and policies in different settings;
 - b. Prerequisites of, and conditions for, their wider dissemination and implementation within and across countries to ensure effective mutual learning/cross fertilisation.
- 4) Suboptimal understanding of the context that is fundamental for a successful transfer and scale up of research and innovations.
- 5) Research and innovations not based on the need of the local, regional contexts or on the end users need, due to lack of knowledge on how to involve users in the entire research and innovation chain.

⁸ https://climate.copernicus.eu/2022-saw-record-temperatures-europe-and-across-world

⁹ https://www.healthdata.org/news-release/lancet-news-release-non-optimal-temperature

¹⁰ https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

¹¹ Preventing the next pandemic - Zoonotic diseases and how to break the chain of transmission | UNEP - UN Environment Programme

The Partnership will focus on addressing (priority) knowledge gaps for an evidence-based approach for pandemic preparedness and where research and innovation (R&I) activities bring added value.

2.1.6 Serving public and private interest

Considering the sudden onset of COVID-19 in Europe, some areas of pandemic preparedness have already seen some great progress whereas progress in other crucial areas is still very slow. This partnership will bring together a diversity of actors within the field of pandemic preparedness and establish a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases, that can respond to them swiftly and efficiently, and that is fully integrated in the wider European institutional Health Security framework. It thereby strongly addresses the challenge to "leave no-one behind".

Despite the willingness of EU Member States to align and coordinate their national programs for infectious disease R&I around a shared strategic research agenda, these efforts encounter obstacles due to divergent national political priorities. The alignment of pandemic preparedness strategies from all Member States will contribute to a more cohesive approach at the European level, ultimately serving the best interests of all stakeholders.

2.1.7 Building on experience of prior R&I EU-funded initiatives

The European Commission has been, and continues to be, at the forefront of supporting research and innovation and coordinating European and global research efforts, including preparedness for pandemics. In particular, the European Commission has invested heavily into research on preparedness and response to infectious disease outbreaks, including for a public health emergency like COVID-19, by:

- investing in developing clinical networks and research infrastructures to ensure preparedness to deliver clinical research,
- boosting epidemiology research and modelling to develop better monitoring systems, and
- launching emergency research funding mechanisms.

Between 2007 and 2019, a substantial investment of €4.1 billion was made through the 7th Framework Programme and Horizon 2020 in infectious diseases research.

Additionally, since the onset of the COVID-19 pandemic, the European Union has been at the forefront of supporting research and innovation, initiating its first emergency call on 30 January 2020, coinciding with the World Health Organization declaring COVID-19 a Public Health Emergency of International Concern. As part of a €1 billion pledge for coronavirus research under Horizon 2020, the European Commission launched several special actions in 2020. These initiatives aimed at addressing epidemiology, preparedness and response to outbreaks, the development of diagnostics, treatments, and vaccines, as well as the infrastructures and resources supporting this research.

Under the Research and Innovation Framework Programme HORIZON EUROPE, the European Commission has reaffirmed its commitment by deploying the most ambitious EU Research & Innovation program ever, allocating a budget of €95.5 billion for the period from 2021-2027 (figure 1).

Figure 1. HORIZON EUROPE budget

Ho	rizon Europe programme structure		Total in € million
	EXCELLENT SCIENCE of which		25 011
y	The European Research Council (ERC)	16 004	
	Marie Skłodowska-Curie Actions (MSCA)	6 602	
	Research infrastructures	2 406	
	GLOBAL CHALLENGES AND EUROPEAN INDUSTRIAL COMPETITIVENESS of which		53 51
ド	Health	8 246	
	Culture, creativity and inclusive society	2 280	
	Civil Security for Society	1 596	
	Digital, Industry and Space	15 349	
	Climate, Energy and Mobility	15 123	
	Food, Bioeconomy, Natural Resources, Agriculture and Environment	8 952	
	Non-nuclear direct actions of the Joint Research Centre (JRC)	1 970	
(K)	INNOVATIVE EUROPE of which		13 59
	European Innovation Council (EIC)		
	European innovation ecosystems	527	
	European Institute of Innovation and Technology (EIT)	2 965	
36)	WIDENING PARTICIPATION & STRENGTHENING THE EUROPEAN RESEARCH AREA of which		3 39
روه	Widening participation and spreading excellence	2 955	
	Reforming and enhancing the European R&I System	438	
TC	OTAL HORIZON EUROPE		95 517

Moreover, in response to the COVID-19 pandemic that highlighted the fragility of national health systems, and to enhance crisis preparedness within the EU, the EU4Health programme was adopted. It will bring a contribution to the long-term health challenges by building stronger, more resilient and more accessible health systems. This programme, with a total funding of €5.3 billion over the next seven years, represents an unprecedented level of financial commitment to improve and foster health in Europe.

The future Partnership on Pandemic Preparedness will not only capitalise the experience and outcomes of the previous projects funded by EU under its different previous programmes but build upon the insights gained from projects funded under its current programmes, notably:

- Research and Innovation Actions funded under Horizon Europe Cluster 1 "Health";
- Research and Innovation Actions funded under Horizon Europe Cluster 6 "Food, Bioeconomy, Natural Resources, Agriculture and Environment";
- European Partnerships under Horizon Europe;
- Joint Actions and other large initiatives funded under EU4Health.

Additionally, the partnership will draw on insights from other initiatives, such as the Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R) and the EU Research Infrastructures.

2.1.8 Key R&I challenges and gaps

Considering the sudden onset of COVID-19 in Europe, some areas of pandemic preparedness have already seen some great progress whereas progress in other crucial areas is still very slow.

Since the 1970s, the rate of emerging or re-emerging infectious diseases in general and those related to zoonotic diseases and vector-borne diseases in particular has been steadily increasing, due to demographic developments, urbanization, increased travels and trade, changes in land use, deforestation, or climate change, including the spatial distribution of species.

In addition to HIV/AIDS which led to a global pandemic in the twentieth century, and viral hepatitis, we have faced major epidemics since 2003: SARS in China, Ebola in West Africa, Chikungunya and Zika in Central and Latin America, and the Caribbean (particularly the West Indies), MERS in the Middle East, and two pandemics: H1N1 influenza and COVID-19. The diversification and spread of resistance to antimicrobial agents, also known as silent pandemic, are also now being observed within and between human and animal populations.

More in-depth studies and a global understanding of emerging events, taking into account the different components and their continuum in a One Health perspective (human, animal, and ecosystems) are therefore crucial. In addition, bioterrorism with intentional release of pathogens continues to be of concern.

One of the major roles of the scientific community should be to anticipate and prevent or mitigate the emergence of new epidemics or pandemics, with a view to limiting their health, economic, and social impact. This requires a perspective that goes well beyond the response to the current crisis, deploying a long-term strategy of coordinated monitoring, preparation, and mobilization of the academic community, public authorities, and industry.

The challenge is twofold: the systematic and generic preparation of the response to future emerging or re-emerging events, while understanding and preventing future emerging or re-emerging events. This research should lead to innovations, by developing new preventive, diagnostic, and therapeutic counter measures, and improve knowledge on public health and social science to implement these countermeasures.

In this context, the concept Strategic Research and Innovation Agenda (SRIA) on pandemic preparedness identifies several key R&I challenges and proposes the associated measures:

Challenges	Associated measures
Suboptimal coordination between academic and industrial ecosystems and between research and innovation	Encourage collaboration, integration and multidisciplinary of research
Insufficient infrastructure, lack of coordination	Strengthen preparedness and response infrastructure
Lack of evidence-based data to support the decision-making process related to Public Health and Social Measures	Increase and fund research in areas of interest
Failures in collecting and using data	Promote digitalization and FAIR databases, shared protocols and secured health data space
Insufficient dialogue between the scientific community and public health authorities, decision makers, and society	Stimulate dialogues and communication, make science more accessible to the general public
Challenges in ethics, integrity and equity in preparation for and in the context of an epidemic	Include humanities and social sciences in the dialogue; boost inclusion of the general public

2.2 Common vision, mission, objectives and expected impacts

2.1 Vision, mission and objectives of the Partnership

The Partnership aims to enhance the EU's preparedness for predicting and responding to emerging infectious health threats. This will be achieved by improving the coordination of funding for research and innovation at the EU, national, and regional levels, directed towards common objectives outlined in an agreed-upon Strategic Research and Innovation Agenda (SRIA), and by strengthening the readiness of the research ecosystem, including infrastructures and networks of "ever-warm" clinical trial sites. The Partnership's efforts will directly align with EU priorities and the UN Sustainable Development Goals.

Moreover, the Partnership seeks to contribute to the development of a coherent European Research Area (ERA). This will empower Member States, Associated Countries, and the European Commission to swiftly and collaboratively support research and innovation in pandemic preparedness. Through a multi-annual Strategic Research and Innovation Agenda with shared objectives, the partners, in collaboration with entities like European Centre for Disease Prevention and Control (ECDC), European Medicines Agency (EMA), and other relevant stakeholders, will identify research and innovation needs for the medium- to long-term.

The Partnership will leverage existing pandemic preparedness networks and work synergistically with HERA and other relevant initiatives. Anticipated collaboration with the private sector will further enhance the effectiveness of these efforts.

For this purpose, the **Vision of the Partnership is:**

To establish a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases, that can respond to them swiftly and efficiently, and that is fully integrated in the wider European institutional Health Security framework.

Long-term Mission

The mission of the Partnership is to foster strategic coordination within Member States, the European Union and private sector resulting in the creation of world-leading and autonomous capacities in research and innovation to prevent, control and respond to (re)-Emerging infectious Diseases making our communities more resilient.

This encompasses a comprehensive spectrum of research, spanning from basic research to gaining understanding of priority pathogens, to pre-clinical and clinical studies for the development and evaluation of medical countermeasures, alongside public health and implementation research for improved preparedness and response measures. Moreover, it entails establishing an EU-wide network of ever-warm clinical trials, primed to swiftly adapt when confronted with the next epidemic or pandemic threat. This concerted effort aims to expedite and enhance response capabilities, ensuring that research efforts are both accelerated and refined to effectively address emerging health challenges.

Objectives

The overall objectives of the partnership are two-fold:

- i) Foster a unified understanding of long-term research and innovation priorities for pandemic preparedness, ensuring coordination among funders, policy-makers and research networks;
- ii) Establish pathways leading to a well-coordinated research and innovation system for pandemic and epidemic preparedness across the EU and its Member States.

Within this framework, the approach to research and innovation is structured around five key priorities:

During inter-epidemic period:

- Accelerate basic and applied research on Emerging Infectious Diseases (EID) in a coordinated and integrative manner.
- Boost health innovation and early development of innovation possibly up to human proof of principle.
- Train, educate and communicate on EID.
- Strengthening research readiness.

At the time of a crisis:

• Research activities to be conducted at the time of a health crisis to support interventions to fight the pathogens for the wellbeing of the European citizens and globally.

The SRIA articulates the proposed priorities and actions around three main areas:

- Understand and prepare (ahead of a pandemic): i.e. increasing scientific knowledge on pandemic relevant matters and contributing to a better prepared research ecosystem and ultimately to better prepared health systems and societies.
- <u>Prevent and anticipate (ahead of a pandemic)</u>: i.e. improving readiness of the research ecosystem including infrastructures needed for basic and preclinical research to provide better prediction models and monitoring capacities, and networks of ever-warm cohorts and clinical sites
- Respond and control (at outbreak of and during a pandemic): i.e. providing guidance on scenarios how to use the research resources in the best possible way for the rapid development of countermeasures, and for optimally implemented monitoring and surveillance systems.

The environmental, social, economic, ethical, and political factors which characterise a social ecosystem influence the emergence of zoonotic infectious diseases. These different determinants must be considered, in animals, humans and the environment, to understand, prevent, anticipate, and better prepare for the emergence of infectious diseases. To act more effectively against emerging diseases, an integrated, transdisciplinary, cross-sectoral approach, supported by stakeholders in human, animal, and environmental health, both in research and in the field (politicians, decision- makers, veterinarians, doctors, civil society stakeholders, etc.), is essential.

These approaches can be presented as a "One Health approach" to help understand, prevent, and prepare to respond to emerging and re-emerging events.]

The partnership activities will focus on the HERA priority pathogens potentially responsible for emerging or re-emerging events, World Health Organisation (WHO) blueprint pathogens and national prioritisation lists, with the exception of antimicrobial-resistant (AMR) pathogens as long as these are not potentially capable of triggering a fast-moving epidemic/pandemic. BE READY fully acknowledges

the threat of AMR pandemics. However, the problem of the slow AMR pandemic will be addressed in detail in other networks/organisations such as the One Health-AMR Partnership.

2.2.2 Expected impacts and outcomes of the Partnership

The expected **impacts** of the Partnerships are:

- 1) establishment of a pandemic preparedness research ecosystem to support a timely research response in case of crisis and reduce the burden of emerging infectious diseases;
- 2) governance structures and procedures in place for timely research prioritisation and funding;
- 3) relevant research for better preparedness implemented on continuous basis to predict and respond to emerging infectious health treats

The **outcomes** of the Partnership are:

- <u>Outcome 1</u>: Research funders, policy-makers and the research community are aligned towards common priorities for R&I in pandemic preparedness and have a common understanding of the R&I gaps to be addressed by a long-term Strategic Research and Innovation Agenda.
- <u>Outcome 2</u>: Evidence-based solutions are available to be prepared, to prevent and to respond to (re)emerging infectious diseases and/or pandemic outbreaks.
 - The scientific community has better understanding of the biology of the pathogens with high pandemic or epidemic potential (virus, bacteria etc.), its transmission, transmissibility, its interaction with humans, animals and plants, in particular in view of emerging threats to human health, such as infectious diseases.
 - Potential/Candidate medical countermeasures to the emerging threats to human health, e.g. vaccines, diagnostics, therapeutics, digital solutions and nonpharmaceutical interventions (NPIs), are identified, developed and evaluated in close collaboration with Competent Authorities at National and EU level.
- Outcome 3: Health authorities have access to evidence-based data and tools to develop policies, strategies and to define Public and Social Health Measures for pandemic preparedness and response.
- Outcome 4: The research ecosystem (research institutions, vaccine and diagnosis development platforms, therapeutic platforms, infrastructures, Cohorts, forecasting and modelling research, adaptive trials; social sciences research networks and community engagement, data sharing, public health implementation research) are in place to enable a timely research response in case of an emergency in a coordinated manner.
 - networks of clinical trial sites with capacity to implement large-scale multi-country trials in different target populations are consolidated, further developed and ready to pivot rapidly when an emergency happens, with the clinical research capacity and the lab capacity being sustained.

- Contributing to the Coordination mechanism to support prioritisation of emergency trials, to identify and rank promising compounds, mobilising EU and Member States funding mechanisms.
- The research community benefits from and uses infrastructures, platforms and networks necessary for fast and timely start of the response research, capitalising on previous investments and existing infrastructures (e.g. ISIDORE, BY COVID) supporting collaboration, trans-boundary access and provision of services.
- The research community benefits from and uses an improved comprehensive knowledge framework integrating the EU, national/regional data and information infrastructures
- The regulatory authorities, scientific community, health care providers and practitioners have access to harmonised and standardized procedures, protocols and templates related with the fundamental, preclinical, clinical and social science research.

2.2.3 Links and/or collaboration opportunities with other Partnerships and European Union programmes

The future Partnership on Pandemic Preparedness will take into account the following and look for synergies and collaboration opportunities with the following EU funding programmes and Horizon Europe Partnerships and Joint Initiatives. This list is based on existing Partnerships and initiatives and will be regularly updated.

Type of Initiative	EU Initiative	Synergies and potential joint activities identified
EU Funding Programmes	EU4HEALTH	Topics within the work programme related to the Partnership's priority areas are, e.g.:
		 Supporting actions regarding epidemiological surveillance, thus contributing to assessment of factors that affect or determine the health of people.
		2. Supporting actions to foster Union-wide health crisis prevention and preparedness, and the management capacity and response capacity of actors at Union and national level, including voluntary stress tests, contingency planning and preparedness exercises; supporting the development of quality health standards at national level, mechanisms for the efficient coordination of preparedness and response, and the coordination of those actions at Union level
		 Supporting actions for setting up an integrated cross-cutting risk communication framework covering all phases of a health crisis, namely prevention, preparedness, response and recovery
		 Communicating to the public in the context of risk management and health crisis preparedness
		5. Supporting investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises
		 Supporting actions for the procurement and supply of essential crisis-relevant products, which contribute to their affordability, in a manner that complements Member States' stockpiling actions.

	 Supporting actions for the preparatory work for mobilising and training at Union level a reserve of medical, healthcare and support staff to be mobilised in the event of a health crisis, in close collaboration with the ECDC, in synergy with other Union instruments, and in full respect of Member State competences; facilitating the exchange of best practices between existing national reserves of medical, healthcare and support staff. Supporting the digital transformation of healthcare and health systems, including through benchmarking and capacity building, for the uptake of innovative tools and technologies such as artificial intelligence, and supporting the digital upskilling of healthcare professionals Supporting the establishment and operation of a health intelligence and knowledge infrastructure Supporting the establishment and operation of a mechanism for cross-sectorial coordination following the One-Health approach Supporting, in synergy with other programmes, clinical trials to speed up the development, market authorisation and access to
	innovative, safe and effective medicinal products and vaccines
Horizon Europe - Cluster 1	Topics within work programme 2023-2024, and in particular its Destinations 3, 4 and 5, related to the Partnership priority areas are e.g.:
"Health"	HORIZON-HLTH-2023-DISEASE-03-04: Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential 2. HORIZON MITTI 2023, DISEASE 03, 05, Dandemic prepared assessed.
	HORIZON-HLTH-2023-DISEASE-03-05: Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort networks HORIZON HITH 2023 DISEASE 03-07: Polationship between
	 HORIZON-HLTH-2023-DISEASE-03-07: Relationship between infections and non-communicable diseases HORIZON-HLTH-2023-DISEASE-03-17: Pandemic preparedness and
	response: Understanding vaccine induced-immunity 5. HORIZON-HLTH-2023-DISEASE-03-18: Pandemic preparedness and response: Immunogenicity of viral proteins of viruses with epidemic and pandemic potential
	HORIZON-HLTH-2024-DISEASE-08-12: Pandemic preparedness and response: Maintaining the European partnership for pandemic preparedness
	 HORIZON-HLTH-2024-DISEASE-08-20: Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential
	8. HORIZON-HLTH-2023-CARE-04-01: Maintaining access to regular health and care services in case of cross-border emergencies
	 HORIZON-HLTH-2023-TOOL-05-04: Better integration and use of health-related real-world and research data, including genomics, for improved clinical outcomes
	 HORIZON- HLTH-2023-TOOL-05-05: Harnessing the potential of real- time data analysis and secure Point-of-Care computing for the benefit of person-centred health and care delivery
	11. HORIZON-HLTH-2023-TOOL-05-08: Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats
Horizon	Topics within work programme 2023-2024, and in particular its Destination 1,
Europe - Cluster 6	related to the Partnership priority areas may be, e.g.:

		HORIZON-CL6-2023-BIODIV-01-17: Interlinkages between biodiversity loss and degradation of ecosystems and the emergence of zoonotic diseases
EU-funded projects under Horizon Europe, Cluster Health	ESCAPE	Stakeholders active in infectious disease modeling, public health risk management and science to policy interactions. Improving data accessibility, Scaling up modeling efforts and facilitating science to policy interaction
	PANDASIA	Pandemic literacy and viral zoonotic spillover risk at the frontline of disease emergence in Southeast Asia to improve pandemic preparedness
	PCR-4-ALL	Impact and viability of a novel mass PCR testing method as a pandemic-fighting strategy
Partnerships	Fostering a European Research Area for Health Research (ERA4Health)	The ERA4Health partnership will mainly support investigator-initiated clinical studies, but also call for proposals on public health needs, in priority areas identified by partners. One of the specific objectives of ERA4Health is focused on new, better, and more cost-effective health services, technologies, tools, and digital solutions. Synergies and potential joint activities lay in the review of common research priorities to complement and create synergies between calls and funded Projects.
	Animal Health and Welfare (EU PAH&W)	PAHW will generate key knowledge, innovative methodologies, tools and products helping to reduce the socio-economic and environmental impact of animal infectious diseases and to strengthen animal welfare in livestock and aquaculture, and will reinforce the preparedness of all actors and stakeholders. Synergies and potential joint activities lay in the review of common research priorities to complement and avoid duplication of activities.
	One-Health Antimicrobial Resistance (AMR)	The AMR partnership will contribute to aligning national research and improving EU coordination of research activities to provide novel solutions for AMR diagnosis, treatment, and control. Synergies and potential joint activities lay in the review of common research priorities to complement and create synergies between calls and funded Projects.
	Innovative Health Initiative (IHI)	IHI aims to accelerate the development of scientific and technological innovations to address unmet public health needs (in a pre-competitive context). The Partnership may contribute to formulating the unmet public health needs, as well as to inform the R&I activities pursued by IHI.
	Global Health EDCTP3 Joint Undertaking	The European and Developing Countries Clinical Trials Partnership (EDCTP) aim is to accelerate the clinical development of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases, including (re-)emerging diseases.
Other EU Funding Instruments	Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R)	 Analysis of related research priorities and sharing of research strategy to avoid duplications. Analysis of funded projects to search for synergies among them.
EU Co-funding Instruments	European Regional	 Supporting of the deployment of initiatives aimed at strengthening research, technological development and innovation in health- related areas.

	Development Fund (ERDF)	Co-funding of the Partnership projects within the regions with linked areas in S3.
	European Social Fund Plus (ESF+)	Investing in the implementation of education, training and lifelong learning initiatives addressed to young researchers and capacity building.
EU Research Infrastructures	European Clinical Research Infrastructure Network (ECRIN ERIC)	Links scientific partners and networks across Europe to facilitate multinational clinical research Provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration. ECRIN will be promoted among the research community to improve actions related to clinical trials.
	European Research Infrastructure for Biobanking and Biomolecular Resources (BBMRI ERIC)	Offers biobanking human biosamples and manage linked to clinical data. Bring together all the main players from the biobanking field — researchers, biobankers, industry, and patients — to boost biomedical research. BBMRI ERIC will be promoted among the research community to receive: quality management services, support with ethical, legal and societal issues, and a number of online tools and software solutions for new treatments.
	Life-Science Infrastructure for Biological Information (ELIXIR)	Holds life science data archives and bioinformatics tools The use of ELIXIR will be promoted by the Partnership to enable users in academia and industry to access services and bioinformatics resources that are vital for their research.
	European Infrastructure for Translational medicine (EATRIS)	Facilitates advancing medical innovations to the market and into the clinics. EATRIS will be promoted by the Partnership to inform researchers on the access to resources and services to translate scientific discoveries into benefits for patients by means of clinical, biological and technological expertise.

2.2.4 Estimated R&I investments necessary to achieve the specific objectives

The Pandemic Preparedness Partnership will be a mixed co-funded partnership comprising both 'inhouse activities' and open joint transnational calls. The in-house activities will be carried out to strengthen the research ecosystem readiness including development platforms, research infrastructures, cohorts, forecasting and modelling research, warm-based clinical trial networks, social sciences research networks in Member States and Associated Countries, and to foster research skills.

The partnership will use the following tools to achieve the specific objectives:

- Develop and update a Strategic Research Innovation Agenda to improve coordination and cooperation to define research and innovation agendas on national and European levels (and contributing globally), as essential part of the pandemic preparedness planning and implementation activities;
- Pool fundings and launch joint transnational calls to support coordination and prioritization of a comprehensive research response to a health emergency, from basic research for better understanding of pathogens with pandemic potential to the development or adaptation of

- medical countermeasures, as well as effective non-pharmaceutical interventions (NPI) and/or public health and social measures (PHSM), and using an integrated One Health approach;
- support the readiness of the research ecosystem and the coordination with the infrastructures needed both in preparedness and response mode including the necessary research infrastructures for basic & pre-clinical research, the consolidation and further development of ever-warm EU-wide networks for clinical research, controlled trials and observational studies for public health interventions, such as EU-wide vaccine and treatment trials, PHSM/NPI trials or cohorts;
- the provision of robust and timely scientific evidence to inform sound public health decision-making in response to a public health emergency;
- the use of agreed data standards¹² to safely collect, store, link and manage FAIR data and to exploit the full potential of the generated data for modelling and in-silico methods for epidemic surveillance, clinical trials and observational studies, among others.

The R&I investments targeted to achieve these objectives of the Partnership is 200 million Euros.

The overall funding will pool Member States and EC funding. Member states will contribute to the partnership through in cash and in-kind contribution. The in-kind contribution will be dedicated to sustain and develop the research ecosystem readiness, in particular the ever-warm clinical trial networks, and infrastructures needed both in interepidemic period and at the time of a crisis.

Member states participating in Joint transnational calls will contribute as well with in cash contributions. Additional funding from volunteer regional funds, associated countries and third parties will be pooled to the joint transnational calls.

The Partnership will use a Monitoring and Evaluation Framework to assess the results and monitor the R&I investments mobilised. Such indicators will include:

- Investment by Member States and European Commission in Research & Innovation on pandemic preparedness via the Partnership;
- Leverage effect of partnership on national investment: Funding (euros) in cash and in-kind contributions declared to the European Commission for the Partnership.

2.2.5 How the proposed Partnership is expected to trigger relevant transformational changes in the broader research and innovation ecosystem

The Partnership will help trigger the expected changes, as it is a unique instrument in capacity to bring together all the stakeholders and institutions involved in pandemic research and innovation at national, regional and European level.

The proposed Partnership will develop internal governance rules, pool fundings and build interpersonal knowledge and trust between the stakeholders involved. The following tools will be used to trigger transformational changes:

- Definition and update of a joint *Strategic Research & Innovation Agenda* will allow to reduce the fragmentation of the research landscape, and coordinate efforts towards shared priorities;

22

¹² Without prejudice to the ones set by the Clinical Trials Regulation EU No 536/2014

- Joint transnational calls: will support excellent research covering the full spectrum of research in a coordinated manner;
- Strengthening and support to the research ecosystem readiness and ability to pivot in a crisis mode in case of an emergency;
- Support to the coordination between Member States around common goals, approaches, and coordinated actions.

The participation of the stakeholders and institutions involved in pandemic research and innovation at national, regional and European level in the governance of the Partnership will reduce fragmentation in the research landscape, mobilize and concentrate resources to meet the priorities defined in the joint *Strategic Research and Innovation Agenda*.

Projects supported by joint transnational calls will improve knowledge of epidemic-risk pathogens in basic, preclinical and clinical research (trials up to phase II-III), enabling the development of medical countermeasures (drugs, vaccines) and diagnostics, and their dissemination to the scientific community.

The Partnership will strengthen the readiness of a conducive research ecosystem which is necessary in the inter-epidemic period to ensure that cutting-edge research can be carried out and which is able to pivot in the event of an outbreak. This will take the form of support in setting up the necessary infrastructures when they need to be reinforced, and of support to coordination between all the infrastructures and elements of this ecosystem, among which basic and preclinical research infrastructures, platforms for MCM development, ever-warm trial networks & cohorts, the data sharing system, social science infrastructures.

In the event of an outbreak, the Partnership will be in position to disseminate knowledge about the disease within the research community, and monitor its natural history by activating existing cohorts or setting up dedicated cohorts to provide researchers with the information they need to develop diagnostics and NPIs. Upstream research on pathogens will contribute to the development of medical countermeasures (therapeutics, vaccines) that can be clinically tested thanks to the supported everwarm European clinical trial networks.

The Partnership will also provide scientific information on public health and social measures and ensure its dissemination to decision-makers so that they can develop strategies and policies based on scientifically established information and tools.

The Partnership will take advantage of its European dimension to boost awareness and training on emerging infectious diseases, enabling public authorities to combat misinformation.

2.2.6 Exit-strategy and measures for phasing-out from the Framework Programme funding

During the development phase of the partnership, when seeking the political commitment at national level for participation, the long-term sustainability will be discussed and the national interests confirmed. With this in mind, the partnership will bring together ministerial representatives and funding organisations to manoeuvre in advance for sustainability. The necessary research infrastructure required for long-term sustainability will be developed in the partnership as part of the sustainability strategy.

A Monitoring & Evaluation framework has been designed. It presents the expected outcomes of the partnership and defines indicators, baselines and targets.

The Partnership will monitor, all along its implementation phase, the impacts achieved in relation to the targets and key performance indicators. This monitoring and evaluation process will provide objective data to identify the most efficient intervention modes. This information will support decision makers to identify which actions would need phasing out measures, and which would be more efficient to be strengthened at the Partnership level. For this purpose, it will be important to ensure a highly efficient communication and dissemination strategy following relevant policy processes to ensure timely input to discussions. A long-term sustainable partnership in Europe should not be reliant on research funds only but requires a wider political endorsement and investments.

In both cases, the guiding principle is that the whole Partnership is greater than the sum of its parts. This principle will be implemented in the development of the exit strategy by considering how each activity relates to the context provided by the partnership and how the Partnership will transition away from this Framework Programme as a whole and as components.

Each activity will have a defined exit and sustainability strategy and stated relationship to the overall Portfolio. The overall exit strategy will describe a range of scenarios including what will happen if an activity is sustained in a successor to the Partnership, or included in mainstream activities, or sustained outside a successor to the Partnership (e.g., funded by national governments) or if the activity is not sustained. This will inform decisions about the place of each activity in the ecosystem, including when and how to support any spinouts. The sustainability strategy will describe which stakeholders will be supporting an activity operation, maintenance and further development, and how the stakeholders will support sustainability – deployment of material, financial, and human resources.

2.3 Necessity for a European Partnership

2.3.1 How the Partnership addresses the objectives of Horizon Europe and common political priorities of the EU and its Member States

"Protecting the health of Europeans and collectively responding to cross-border health crises" is one of the main pillars of the political priority of the Commission "Promoting our European way of life". The Partnership will be firmly anchored within the framework of the European Health Union¹³ that aims to improve the EU's capacity in the vital areas of prevention, preparedness, surveillance, risk assessment, early warning, and response under this political priority.

The partnership's activities will also support the EU Global Health Strategy, notably its guiding principle 5 to boost global health research and guiding principle 7 to strengthen capacities for prevention, preparedness and response. The Partnership will expand and strengthen European and global research preparedness and response capacities to address new and emerging pathogens.

The Partnership will contribute to the United Nations Sustainable Development Goals, to which the EU is committed to implement in all policies, in particular the **SDG n°3** "Ensure healthy lives and promote well-being for all at all ages" thanks to the contribution to the coordination of research at EU, national and global level, the support to the development of knowledge on potential communicable diseases and the support to the development of potential countermeasures.

The Partnership on pandemic preparedness will address several objectives of Horizon Europe:

- "Creating a more resilient, inclusive and democratic European Society", key strategic orientations D for EU research and innovation for the period 2021-2024. The COVID-19 pandemic has confirmed and further highlighted the importance of planning and investing in research and innovation before a health crisis occurs. The Partnership will contribute to promote and protect human health and well-being by fostering alignment and coordination in order to prevent communicable diseases and decreasing the burden of diseases on people and communities. It will contribute to strengthen the ability of EU Member States to prevent and detect early any threats to public health as well as to strengthening their preparedness to respond promptly and effectively to public health emergencies thanks to research and Innovation for the development of countermeasures (diagnostics, therapeutics, vaccines) and by providing health authorities with evidence-based data on Public Health and Social Measures. It will also increase the resilience of EU Member states' health care systems.
- Promoting an open strategic autonomy by leading the development of key digital, enabling and emerging technologies, sectors and value chains, Key strategic orientation A of the Horizon Europe Strategic Plan 2021-2024:
- The Partnership will contribute to safer, trusted, more effective and efficient, affordable and cost-effective tools, technologies and digital solutions for improved disease prevention, diagnosis, treatment and monitoring through the development and update of a Strategic Research and Innovation Agenda, support to basic research and innovation. It will integrate patient's association in the design and decision-making on expected health outcomes and

 $[\]frac{13}{https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en}$

potential risks involved. The basic and translational research will also contribute to ensure European leadership in breakthrough health technologies and open strategic autonomy in essential medical supplies and digital technologies, contributing to job creation and economic growth.

Dialogue and collaboration between Member States, relevant organisations and stakeholders before an outbreak are key to support international and national research plans and infrastructures. In this view, the Partnership will contribute to building a European Research and Innovation Area (ERA) to rapidly and jointly support research and innovation in pandemic preparedness. For this purpose, the main goal of the Partnership is to establish a consolidated research and innovation framework to improve the EU's preparedness to predict and respond to emerging infectious health threats by better coordinating funding for research and innovation at EU, national (and regional) level towards common objectives and an agreed Strategic Research and Innovation Agenda.

The Partnership also tackles several <u>Destinations of the Cluster health</u> of the Work Programme 2021-2024 of Horizon Europe:

"Destination 3 - Tackling diseases and reducing disease burden: Health care providers are able to better tackle and manage diseases (infectious diseases, including poverty-related and neglected diseases, non-communicable and rare diseases) and reduce the disease burden on patients effectively thanks to better understanding and treatment of diseases, more effective and innovative health technologies,"

Thanks to: I) the acceleration of basic knowledge on EID, ii) the identification of candidate countermeasures (treatments, vaccines, diagnostics), i and by sustaining clinical trial readiness for public health emergencies.

"Destination 4 - Ensuring access to innovative, sustainable and high-quality health care: Health care systems provide equal access to innovative, sustainable and high-quality health care thanks to the development and uptake of safe, cost-effective and people-centred solutions, with a focus on population health, health systems resilience, as well as improved evidence-based health policies"

<u>Thanks to</u> the support to scientific evidence-based implementation of policies and Public Health and Social Measures

- Destination 5 - Unlocking the full potential of new tools, technologies and digital solutions for a healthy society: Health technologies, new tools and digital solutions are applied effectively thanks to their inclusive, secure and ethical development, delivery, integration and deployment in health policies and health care systems

<u>Thanks to</u> I) the support to the development of potential countermeasures until the proof of concept and preclinical phase, the capitalisation and dissemination of scientific knowledge to facilitate its translation into innovative solutions, ii) the connection with initiatives promoting Data analytics, AI, Robotics for smart and Phygital solutions to assist understanding, iii) tracking, monitoring and management of pandemics in synergy with existing databases and IT platforms and the future EU Health Data Space

Destination 1 - Staying healthy in a rapidly changing society: Citizens of all ages stay healthy and independent in a rapidly changing society thanks to healthier lifestyles and behaviours, healthier diets, healthier environments, improved evidence-based health policies, and more effective solutions for health promotion and disease prevention.

<u>Thanks to</u> the support to scientific evidence-based implementation of policies and Public Health and Social Measures, ii) a better dissemination and uptake of evidence across the broader public to tackle misinformation,

2.3.2 How the partnership will establish a meaningful collaboration with Member States /Associated Countries and relevant national/regional authorities

Horizon Europe encourages the collaborative links in Europe to contribute reducing the R&I divide. In particular collaboration at the EU and international level for research is largely recognised as essential to progress in the development of more efficient and sustainable workflows in the health systems, diagnostic means and pipelines, high quality evidence-based treatments, cure and care, channels for collaboration of the different stakeholders and mutual benefits for all the actors in the pandemic preparedness ecosystem, to make a real difference.

A co-funded Partnership is the best instrument to support a meaningful collaboration among countries. The EU added value of aligning common activities lies in a more efficient use of existing (human, infrastructures, financial) resources as well as knowledge, data and best-practice transfer between countries. Even though research and innovation have the power to uncover the knowledge and develop the technologies to serve individual and societal well-being, economic prosperity (while preserving equity) and environmental sustainability, this ambition can only succeed through an extensive collaboration of Member States and internationally. Indeed, reaching meaningful impacts requires a portfolio approach encompassing a broad range of activities, including strategy, networking, excellence research funding, rapid translation, data sharing, training, prioritisation and support for innovation and dissemination. In this view, the COVID-19 pandemic has shown the importance of effective coordination among EU Member States in the area of health, opening the door to a strong European Health Union, where, among others, countries work together to improve prevention, diagnosis, treatment and aftercare for any disease.

Based on a shared and co-constructed SRIA, the Partnership will reconcile needs whilst pooling resources from different sources. It should foster consortium building and help leverage between existing initiatives of partners under common broader or specific objectives. This will give direction and shape a common implementation strategy. Moreover, the coverage of the Partnership necessitates a level of integration and trans-border multidisciplinary research cooperation that can hardly by covered without a joint effort and a strong commitment of the EU and Members States and Associated Countries.

Therefore, a European Partnership would be more efficient than Horizon Europe calls because it commits the various relevant actors to address the whole chain of research and innovation in a coordinated way and in close cooperation with all relevant actors (from the elaboration of a shared SRIA, the generation of new knowledge to its transfer to end-users for a rapid and concrete implementation at local scales). With a systematic approach to the exploitation of Partnership outputs, it will support the linkage of science and policy. It also requires the alignment and/or integration of different research and innovation agendas and of EU and national programmes, coordination of funding agencies and commitments to implement a long-term strategy that would deliver major changes and impacts. In particular, the partnership will be a unique opportunity to bring together

policy makers, funders, researchers and all stakeholders of the health and care ecosystem. By aligning research and innovation funding through the SRIA and coordinating with non-research and innovation activities, available resources will focus on those priority areas where joint learning has greatest added value ensuring the knowledge translation needed to best support decision making at services and system level.

2.4. Partner composition and target groups

2.4.1 How will the Partnership build upon, strengthen and/or expand collaboration networks and initiatives that are currently existing at the EU level, beyond currently existing Partnerships

To ensure coherence and complementarity of activities and leverage knowledge and investment possibilities, the partnership will establish collaborations with the European Commission services, with other Horizon Europe projects, partnerships (institutionalised and co-funded) and missions as set out in the working document on 'Coherence and Synergies of candidate European partnerships under Horizon Europe' as well as to explore collaborations with other relevant activities at EU and international level. On top of this, the Partnership will develop synergies with EU programmes, including, the Digital Europe Programme (DIGITAL)¹⁴, the European Social Fund Plus (ESF+)¹⁵, the European Regional Development Fund (ERDF)¹⁶, InvestEU¹⁷, the Recovery and Resilience Facility (RRF)¹⁸ and the Technical Support Instrument (TSI)¹⁹.

The European Partnership on Pandemic Preparedness will take into account new EU health institutional framework and build upon the collaboration networks and initiatives currently existing at the EU level.

It will build strong links with the European institutional actors and organise a structured dialogue in the implementation of the partnership. These actors are:

- The European Center for Disease Control: the ECDC can issue recommendations to Member States regarding health threats preparedness, host a new excellence network of EU reference laboratories and establish an EU Health Task Force for rapid health interventions in the event of a major outbreak
- The European Medicine Agency: is able to closely monitor and mitigate shortages of medicines and medical devices during major events and public health emergencies and facilitate faster approval of medicines which could treat or prevent a disease causing a public health crisis
- The European Commission and specially Directorate DG Research and Innovation, DG Santé, and HERA
- One Health cross-agency Task Force: this recently established structure will ensure strategic coordination with One Health approach across several EU agencies²⁰

The Partnership will also take into account the EU policies and initiatives that are ongoing such as:

- The pharmaceutical strategy: The pharmaceutical strategy aims to modernise the regulatory framework and support research and technologies that reach patients. It rests on four pillars:
- ensuring access to affordable medicines for patients, and addressing **unmet medical needs** (in the areas of antimicrobial resistance and rare diseases, for example);

¹⁴ https://digital-strategy.ec.europa.eu/en/activities/digital-programme

¹⁵ https://ec.europa.eu/european-social-fund-plus/en

¹⁶ https://ec.europa.eu/regional_policy/funding/erdf_en

¹⁷ <u>https://investeu.europa.eu/index_en</u>

¹⁸ https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resilience-facility en#the-recovery-and-resilience-facility

¹⁹ https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/technical-support-instrument/technical-support-instrument-tsi en

one-health-cross-agency-task-force.pdf (europa.eu); https://doi.org/10.1016/j.onehlt.2022.100464

- supporting **competitiveness**, **innovation and sustainability** of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;
- enhancing **crisis preparedness and response** mechanisms, diversified and secure supply chains, address medicines shortages;
- ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The Research and innovation undertaken through the activities of the Partnership should allow to develop candidate medical countermeasures that answer to unmet medical needs.

- European Health Data Space

The European Health Data Space is one of the central building blocks of the European Health Union and a milestone in EU's digital transformation. It aims to:

- improve healthcare delivery across the EU, by empowering people to control their health data in their home country or in other EU countries;
- offer a consistent, secure, trustworthy and efficient framework for the use of health data.
 Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data, crucial to developing life-saving treatments, vaccines or medical devices;
- foster a genuine single market for digital health services and products;
- fulfil unmet medical needs;
- support a competitive and innovative European pharmaceutical industry;
- enhance resilience through diversified supply chains, environmental sustainability, and crisis preparedness;
- promote high standards for medical products globally.

The European Partnership will build on the gaps and unmet needs identified by the European health Data Space, exchange on regulatory issues in the elaboration of protocols in trials and clinical research. The data infrastructures and data sets might support the research realised in the framework of the Partnership.

- **Global health security:** To improve global health security and deliver better health for all in a changing world, the Commission adopted a new **EU Global Health Strategy** in November 2022.

The Strategy positions global health as an essential pillar of the EU's external policy. It promotes sustainable, meaningful partnerships of equals drawing on the Global Gateway. As the external dimension of the European Health Union, the strategy is designed to guide EU action for ensuring better preparedness and response to health threats.

The Partnership will take into account the international strategy of the EU. The Partnership aims at bringing international actors, associated countries and potential partners around its priorities and to build synergies.

State of Health Preparedness:

Since 2022, the European Commission publishes a *State of Health Preparedness Report* every year. The report presents a mapping of the EU actions that have been put in place to address serious cross-border health threats, with a focus on those actions implementing Regulation (EU) 2022/2371. It highlights the progress made in the fields of preparedness and response. It identifies the challenges

facing public health authorities and outlined concrete actions that the Commission will take to address them. State of Health Preparedness Report.

The Partnership priorities and actions will take into account the information reported in the *State of Health Preparedness* in particular the gaps and needs identified.

2.4.2 Justify the type and composition of partners (public, private, foundations etc.) considered necessary for this partnership and describe the ambition to include new types of partners (in particular end-users), and to ensure the necessary thematic and geographical coverage to meet the objectives

The partnership will be open to all EU Member States, as well as to countries associated to Horizon Europe and will remain open to third countries wishing to join.

The Partnership will be composed of organisations of public domain including Research funding organisations, national Research and Health authorities, EU-wide networks and infrastructures for clinical research, controlled trials and observational studies for public health interventions, such as EU-wide vaccine and treatment trials, PHSM/NPI trials or cohorts, research performing organisations identified by Member States or Associated countries. They will encompass expertise and policy area ranging from Public Health Organisations, Ministries of Science and Health, Innovation to organisations for Environmental matters. All partners will have a key role in their respective countries in preparedness and response activities. A larger community of stakeholders, EU and International initiatives related to Pandemic Preparedness will be closely linked to the initiative.

The Partnership will establish a formal and regular collaboration with other relevant research and innovation (R&I) initiatives to secure an optimum level of interconnections and ensure effective synergies. The strategic planning process of Horizon Europe with the early identification of priorities for partnerships and coordinated preparation process has created a unique opportunity to identify the priorities for collaboration and synergies ex ante. In this view, approaching multilateral fora such as G20 and G7 initiatives, UN SDGs actions, and other European and international level research and innovation initiatives, such as e.g. GloPID-R, WHO R&D blueprint, ACT-Accelerator, EU Health Data Space, Innovative Health Initiative, the expected future European partnerships on Transforming Health and Care Systems, One Health antimicrobial resistance, ERA for Health research and Animal Health and Welfare, or other relevant projects funded under Horizon 2020 or Horizon Europe, will be crucial.

For this purpose, building on the experience of consortium partners who participate in, and in some instances coordinate, manifold European and International initiatives and instruments across the health&bio science and technology, a database of relevant EU-level and international projects and activities, objectives and contacts will be created and constantly updated. Before approaching EU/international initiatives identified, an analysis of potential synergies and collaborations with them will be performed in order to ensure a targeted cross-talk aimed at providing inputs on (1) what kind of common activities can be developed, (2) how can the different action plans be aligned and (3) how a sustainable cooperation can be reached, that will be fundamental for the development of the Partnership proposal.

The Partnership will maximise its impacts by involving all relevant partners and stakeholders beyond the narrow composition of core partners and by remaining open during its lifetime. In this view, establishing a dialogue and promoting networking and synergies with all relevant actors in the area of pandemic preparedness will be crucial to foster transparent communication, increase mutual awareness and trust for the benefit of the Partnership.

The identification, contact and dialogue with potential national and funding organisations will be explored firstly from countries already involved in the Partnership but also from those that are not yet partners of the project. The Partnership will target attention to organisations within the EU, as well as in other parts of the world. Collaboration with the latter will be pursued, not only because they may face similar challenges, but most importantly because they may have developed solutions of potential value to Europe, and vice versa. Using existing contacts of the consortium as a whole as potential "entry points", targeted stakeholder will be involved via face to face meetings or predominantly by electronic/technological means as well as by inviting selected experts in the area of pandemic preparedness to attend key meetings concerning Partnership activities.

2.4.3 Describe the envisaged target groups / stakeholder community (beyond the members of the Partnership). Elaborate also on the international dimension and justify the EU- added value including international partners and stakeholders, and provide a justification when specific strategic needs at European level should restrict the international dimension

The Partnership will involve key stakeholders and interested parties, including the research and innovation community, public health authorities, patients and citizens, health and care professionals, formal and informal care organisations, innovation owners, and relevant EU entities.

The envisaged target groups and stakeholder community include the following actors involved in pandemic preparedness:

- Researchers and scientists;
- Policy makers;
- National and EU wide networks and infrastructures for basic, preclinical and clinical research, controlled trials and observational studies for public health interventions, such as EU-wide vaccine and treatment trials, PHSM/NPI trials or cohorts
- End users and Patient's association;
- Citizens;
- Representatives of Research infrastructures;
- Data sharing platforms / organisations;
- European programmes or initiatives;
- International organisations.

A Stakeholder Board will be dedicated to fostering exchange and cooperation between these actors and the Partnership. A list of identified key initiatives and networks is in Annex I.

3. Planned implementation

3.1. Activities

3.1.1 Achieving the Partnership Objectives

The general objective of the Partnership Pandemic Preparedness is to improve EU's research preparedness to predict and respond to emerging infectious health threats and to reduce the burden of emerging infectious diseases. To structure the work and to ensure engagement four main pillars are proposed:

Pillar 1- Align research on pandemic preparedness

Research funders, policy-makers and the research community are aligned towards common objectives for R&I in pandemic preparedness, and have a common understanding of the gaps and long-term Strategic Research and Innovation Agenda. This means that a Strategic Research Innovation Agenda with common objective for R&I in pandemic preparedness will be available and regularly updated. A collaboration framework among the partners will be built and maintained providing the ground to actively engage with HERA, relevant stakeholders and other initiatives in the area of pandemic preparedness at EU and international level.

Pillar 2 - Boost research: funding excellent and innovative research

Excellent research and development will be supported through annual joint transnational research calls and other funding activities. Those activities can cover the following areas:

- 1) Basic Research
- 2) Pre-clinical Research
- 3) Clinical Research
- 4) Research in Public Health

Pillar 3 – Support research ecosystem readiness

Supporting EU-wide infrastructures, adaptive trials and cohorts will enable clinical research preparedness to enhance a timely and coordinated clinical research response in case of an emergency. The foster this ever-warm networks of trial sites are consolidated, further developed and ready to pivot rapidly when an emergency happens, with the clinical research capacity and the lab capacity is sustained.

Pillar 4 – Fostering research and innovation skills

Transversal activities to foster research and innovation skills will include:

- 1) Capacity building in EU countries, especially those that are underrepresented in the pre-clinical and clinical research landscape and social science for pandemic research
- 2) Support to the knowledge exchange on research results, translation of research into policies and implementation of research results in practice
- 3) Ensure societal engagement by bridging science to society creating awareness of pandemic preparedness challenges, environment and one health approach
- 4) Facilitate sharing, use and reuse of FAIR data.

- 5) Communication and dissemination.
- 6) Training activities for research talents in pandemic preparedness

3.1.2 Mechanisms which will ensure the complementarity

Ensuring the development and deployment of R&I strategy and recommendations at all levels (national, EU and international) is essential for the efficient and agile advancement of the Pandemic Preparedness Partnership towards expected outcomes and impacts.

The overall and annual planning of the Pandemic Preparedness Partnership will be driven by the preestablished SRIA to be developed and validated by all stakeholders, possible updates of which will be overseen by dedicated Governance Bodies of the Partnership, which will be key to the implementation of the activities fostering alignment of and with EU, international and national policies, strategies and initiatives. In particular, the SRIA will seek to aligning European, national, and regional strategic priorities and strategies but will also be the basis for developing the Partnership Annual Work Plans. These will cover yearly specific priorities for R&I to be addressed for implementation. R&I priorities will be selected taking into account the needs of ensuring complementarity of activities and helping avoid unnecessary duplications with other relevant initiatives of Horizon Europe and beyond.

To that end, the Partnership will foresee specific activities aimed at actively engaging with relevant stakeholders and initiatives in the area of pandemic preparedness at EU and International level to maximise the alignment and capture opportunities for joint, international actions. These activities will be further complemented by the advices and inputs provided by dedicated Advisory Boards of Partnership which will, inter alia, support the selection of topics for the Joint Transnational Calls and the development of the Partnership Annual Work Plans.

3.1.3 Synergies with national (sectorial) policies, programmes and activities.

The Pandemic Preparedness Partnership will be a unique initiative gathering European Member States, Associated countries, the European Commission, and European agencies such as the ECDC and the EMA around a common Research and innovation Agenda, and joint activities to implement it.

Better prepare to respond to health emergencies will imply, in its DNA, to ensure synergies with national policies in the definition of Research and innovation priorities, in the preparation of programmes and in the implementation of activities between the different partners.

The Partnership will set-up a cooperation framework between experts, researchers, scientists, decision-making stakeholders in pandemic preparedness across Europe and organised regular meetings. This structured and strengthened cooperation framework will contribute to build interpersonal knowledge, build trust, which facilitate the strengthening of collective capacities of health care systems and their ability to act in time of a crisis.

The Partnership is expected to become a knowledge hub regarding Research and Innovation strategies and stakeholders. It will map and regularly update relevant stakeholders at regional, national and EU level, their policies, strategies and activities.

The elaboration of the draft proposal is based on an inventory of national policies, programmes and activities and to identify the initiatives lead and funded at national, and to build on existing programmes and infrastructures. Such mapping will be undertaken during the implementation of the Partnership at least before the preparation of each annual Work Programme.

The support to ever-warm clinical sites and networks is based on the existing programmes and networks existing at national and EU level identified by national authorities. The Partnership will strengthen the links between these sites, support their coordination at an operational and regulatory level, in order to be in position to manage multicentric clinical trials in case of a health emergency.

The approach in the construction of the Partnership is based on the designation of the relevant stakeholders and focal points by national authorities in EU Member States and Associated countries.

A first effort can be seen in the WP3.1 report on knowledge gaps and the SRIA. This will be updated regularly. It has relied on a mapping of EU Member states and Associated countries Research agendas and initiatives to support research on emerging infectious diseases and Public Health and Social Measures.

Members of the BE READY consortium, Research and Health Ministries, National Institutes of Public Health, Research funding organisations have shared the documentation identified and available at national level directly and through online surveys (see Annex II).

EU Member States and Associated countries which were not participating in the CSA have been reached through the presentation of the preparation of the SRIA on Pandemic preparedness to the Members of the Health Programme Committee of Horizon Europe and to the HERA Advisory Board.

3.2. Resources

3.2.1 Types and levels of contributions from partners necessary to achieve the objectives and impacts (financial contributions, in-kind contributions, activities/resources linked to market, regulatory, societal or policy uptake, broader investments)

The Partnership will aim at contributing to following expected outcomes:

- a valued network of clinical trial sites that have the capacity to implement well-coordinated large-scale multi-country quality trials in different target populations, which are able to smoothly transition to public health interventions relevant for cross-border health threats in response to a public health emergency is in place;
- Relevant EU and national entities, the scientific communities and networks, policymakers and funders enhance their collaboration and coordination for strengthened research on pandemic preparedness and response, forming a strong and structured ecosystem with shared evidence, tools and methodologies cutting across sectors;
- Research funders, policymakers, relevant EU and national entities, and the research community recognise and close rapidly relevant research and related infrastructure gaps and break existing silos on pandemic preparedness research and response;

- Healthcare authorities, regulatory authorities, policymakers and other stakeholders use the
 research results to develop evidence-based strategies and policies for pandemic preparedness
 and response, and deploy good practices to European countries and regions, and beyond
 whenever relevant;
- The research community at large benefits from and uses an improved comprehensive knowledge framework integrating the EU, national/regional data and information infrastructures to improve transnational research in the area of pandemic preparedness and response;
- The EU is strengthened as an internationally recognised actor for pandemic preparedness research and response, as such substantially contributing to global cooperation and coordination.

To reach these impacts the Partnership will pool the necessary cash and in-kind resources from the participating national (or regional) research programmes, in order to:

- implement joint calls for transnational proposals resulting in grants to third parties. Financial support provided by the participants to third parties is one of the activities of this action in order to be able to achieve its objectives;
- sustain and further develop the EU research ecosystem readiness in particular the ever-warm clinical trial networks, and infrastructures needed both in interepidemic period and at the time of a crisis.
- support the network of ever-warm clinical trial sites by running continuous preparedness trials in relevant target populations. This support will include the valorisation of expenses incurred by Member States to run these sites such as:
 - Human resources and project office costs at national level to coordinate the relation with the national clinical sites;
 - Human resources for Research Staff: researchers (Principal Investigators (Pis) sub-Pls), research coordinators, and nurses (tasks e.g. recruitment, obtaining informed consent, data collection, and monitoring participant safety), and Human resources for Data Management and Statistical Support Systems for collecting, managing, and analysing trial data
 - Costs incurred for recruitment and management of trial population;
 - Costs linked Infrastructures, facilities and equipment;
- ensure coordination and networking activities with research infrastructures needed in interepidemic period and at the time of a crisis;
- conduct capacity building activities;
- implement coordinated activities between (a group of) partnership members, that contribute to the achievement of the partnership's objectives.

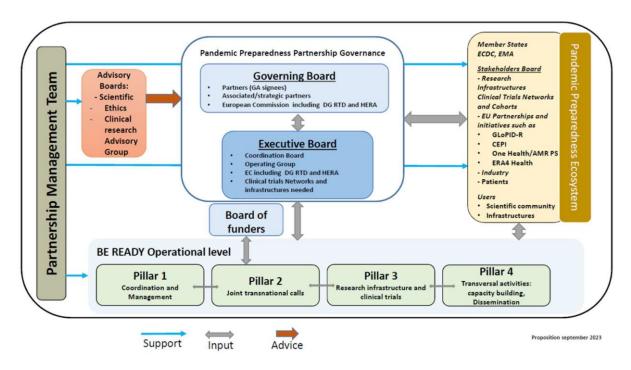
Research projects resulting from coordinated national calls are envisaged as well.

3.3. Governance

3.3.1 Governance and management of the Partnership, including advisory structures and mechanism to be established

An initiative like the Pandemic Preparedness Partnership needs to establish clear roles and responsibilities in order to meet the objectives and to build mechanisms to prevent and solve potential conflicts. Overall the governance structure should be the backbone for transparent decision-making processes with well-defined responsibilities in the governing bodies.

The proposed draft governance structure (figure X) should be further developed with the partners of the future Pandemic Preparedness Partnership. There is a willingness to keep the governance as simple as possible to avoid adding to the complexity of the Partnership and concentrate efforts and resources on developing solutions and maximizing impacts. The different governance bodies are outlined below while the concrete functioning, the main tasks and working processes in the partnership, the role of the BE READY members, associated partners, the European Commission/HERA, the Advisory Boards as well as the surrounding Pandemic Preparedness Ecosystem will be described in detail during the further development of the partnership proposal.



DRAFT GOVERNANCE Figure

The Governing Board (GB) is the strategy/decision making body. The GB consists of three groups (Grant agreement (GA) signees; associated/strategic partners, European Commission/HERA) of representatives with slightly different rights in respect to decisions. GA signees are BE READY partners receiving EU contributions (= beneficiaries). Beneficiaries decide on strategic matters as well as on budget allocations, ensuring and supervising effective operation and deployment of activities and achieving the partnership's objectives. Associated/strategic partners are BE READY members participating in the partnership without receiving EU funding. Associated/strategic partners are

involved in all strategic decisions, but are not allowed to take decisions on the use of the EC contribution, i.e. budgetary issues, proposal reporting, proposal implementation. The role of **EC/HERA** needs to be further determined.

An **Executive Board (EB)** drives the <u>operational level</u>, which implements the strategy defined and issued by the GB and monitors the advancements of the Partnership activities. The **EB** will be responsible for regularly checking the implementation of the GB decisions, preparing recommendations for GB review/considerations and operationalizing the execution of the work programme and (temporary) activities, if necessary. The **EB** is composed of:

- The **Coordination Board** is composed of the Coordinator and two co-Coordinators. The co-coordinators are elected by the GB on a 2-year term basis.
- The **Operating Group** is composed of the Work package Leaders and co-Leaders.
- Representatives from EC (DG RTD and HERA)
- Representatives of Stakeholders Boards like (i.e. research Infrastructures needed in preparedness and at the time of a crisis, and Clinical trials)

The **Partnership Management Team (PMT)**, usually affiliated to the organisation of the coordinator, which will ensure the day-to-day operational management of the Partnership activities, in particular efficient coordination between the different bodies and supporting the exchanges between them. It will also be in charge of communication and support in assisting the Partnership members with the implementation of Partnership activities.

Different **Advisory Boards** will give advice to the partnership:

- an **External Advisory Board** will have overarching expertise on pandemic preparedness and will give advice on the overall coherence of the partnership and support in scientific issues;
- a **Clinical Research Advisory Board** would be consulted in relation with the "clinical research" operational activity.

If further advice on specific matters arises during the lifetime of the partnership temporary or permanent advisory boards will be installed.

The **Board of Funders (BoF)** will be the ultimate decision maker with regards to funding activities for projects. The **BoF** will be composed by one representative per Research Funding Organisation. The EC will be full member of the Board of Funders whenever EC funding is activated. This comprises i.e. the design of the call, timelines, call texts and topics, guidelines and rules for participation and topics selection.

3.3.2 How the governance structure will contribute to ensuring coherence and synergies with the EU research and innovation landscape and demonstrate, as well as transparency and openness during the Partnership as regards the identification of its objectives, priorities, vision, Strategic Research and Innovation Agenda (SRIA) and work programmes.

To ensure coherence and create synergies within the research and innovation landscape, to advance successfully in implementation according to the SRIA, and to complement to the work proposed with others, the Partnership will interact with the External Advisory Board as well as with all relevant players of the existing pandemic preparedness ecosystem. In addition, the partnership will keep on addressing

the coordination with HERA and the European Union Health Institutions as well as establishing collaborations and synergies with stakeholders and other relevant initiatives.

3.3.3 The role of European Commission in the Partnership

The Partnership will be developed and implemented jointly with the European Commission and particularly with DG RTD and HERA. The EC will be a member of the Partnership and be represented on the relevant governance bodies (see 3.3.1). This will allow the Partnership to be closely linked with the most appropriate EU objectives.

3.4. Openness and transparency

3.4.1 Partnership transparency and openness

The Partnership will maximise its impacts by involving all relevant all relevant organisations in its structure as members, associated partners and stakeholders, aiming to broaden participation beyond the narrow composition of core partners already involved in the BE READY CSA and by remaining open during its lifetime. The identification, contact and dialogue with potential national and funding organisations will be explored both with countries already involved in the preparatory CSA and with those that are not yet partners of the project. The partnership seeks the involvement of all EU Members States, independent of in the maturity of pandemic preparedness within their R&I or healthcare systems. For such purpose, the CSA BE READY has already been presented to all EU Member States and Associated Countries during the Health Programme Committee of the 2nd of February 2023, December 7th 2023, and to the HERA Advisory Forum on the 21st of March 2023. The Partnership will build on these first contacts to engage with all Member States and Associated countries.

The partnership will seek the involvement of all EU Members States and regions and/or international partners, as well as involvement of pandemic preparedness related initiatives and others. The stakeholder group will integrate their perspective but also to include all relevant key players that could benefit from the partnership's outcome. As the Partnership will foresee different levels of participation, involvement of external stakeholders will be possible anytime and will be actively pursued and highly welcome without compromising the ownership and commitment of Partnership Consortium Through this approach, the Partnership will ensure a full-inclusive approach which will include the active participation of the whole multi-stakeholder research ecosystem, and in particular: I) Research funders, ii) Research and innovation communities including EU research infrastructures), iii) research outputs users (like patients and citizens, patient organisations, health care professionals, researchers); iv) EU-wide and national policy makers, regulatory authorities. In this view, the Partnership will not only target its attention to organisations within the EU, but also to the ones in other parts of the world. Collaboration with the latter will be pursued, not only because they may face similar challenges, but most importantly because they may have developed solutions of potential value to Europe, and vice versa.

The partnership will remain open to new members during its whole lifetime and across different activities, and specific efforts will be developed to ensure a good geographic coverage within the Partnership with special focus on countries in Europe not (sufficiently) represented. In this view, establishing a dialogue and promoting networking and synergies with all relevant actors in the area of

pandemic preparedness (ecosystem) will be crucial to foster transparent communication, increase mutual awareness and trust for the benefit of the EU Partnership on Pandemic Preparedness. For such purpose, in addition to the Partnership members, a broad range of stakeholders will have the possibility to participate within the Partnership through a dedicated Board. By setting-up this Board through an open and transparent process, the Partnership will create favourable conditions to engage all relevant sectors from the society and will ensure that a broad range of actors can effectively participate in its activities. This approach will allow to integrate their perspective but also to include all relevant key players that could benefit from the Partnership outcome.

The Partnership plans to develop an open access publication strategy for the partnership itself (by sharing strategic documents and outcomes) including recommendations around openness and transparency for the pandemic preparedness community, as well as for results obtained during the joint funding activities that will have to follow the <u>FAIR</u> principles.

Different means of communication and dissemination strategies adapted to the different stakeholders and players will be developed. Furthermore, a dedicated partnership website and social media will allow to maintain an information channel and share information about the work plans, protocols, data, results, strategic developments and other outcomes.

Other possibilities to inform and engage stakeholders will be explored, if applicable and feasible, in due time. Creating synergies is one essential objective of the partnership including consultations of the Pandemic Preparedness community around the entire value chain and allowing new organisations to enter, participate in and benefit from its activities, and add value to the partnership.

Considering, the long funding duration and a steadily advancing Pandemic Preparedness ecosystem, the Partnership will act in a dynamic way, adjust its focus areas over the time span of the partnership and take advantage of emerging opportunities during the lifetime of the partnership. By following well defined annual work plans while simultaneously being responsive and allowing a level of flexibility, the Partnership will adapt approaches to the key bottlenecks in pandemic preparedness.

3.4.2 Non-discriminatory access to the Partnership and Recruitment

Values, including the non-discrimination principle stand at the heart of the Partnership. Discriminations in health disease outbreaks remain in itself an important issue, and the Partnership will dedicate specific attention to prevent any discrimination.

The Partnership will promote equality between people and prevent all discrimination on grounds of gender, age, ethnic origin, religion, conviction, sexual orientation, disability, being in the design or implementation of the activities as well as in the functioning of the Partnership.

In this view, a clear and transparent governance will be set-up from the beginning of the Partnership, allowing the participation from a broad range of actors in the Partnership, with no unjustified barriers.

After the start of the Partnership, the consortium will actively strive to widen the Partnership and will continue its efforts to mobilize additional partners. A pro-active policy will be set-up to:

- improve the geographical coverage of the Partnership for countries associated to Horizon Europe: if some countries are not participating in the Partnership, it will actively try to engage with them and to convince them to become members, with a view to improving the joint programming of research between countries;
- ensure that both research programmers and funders and policy makers in the health research field are represented in the Partnership. The participation of these two types of actors is

crucial to ensure a link between research and policy/implementation, to better take into account and integrate research and policy making temporalities and to improve the uptake of knowledge to support policies and actions. Pro-active actions will be taken to attract actors which might initially be missing from some countries;

• enlarge the Partnership with non-European countries through a pro-active and step-by-step approach: the Partnership will first engage with these countries through specific activities, such as joint calls. Successful collaboration might consequently lead to full membership.

The Partnership will also include specific activities that would be needed to ensure inclusiveness and the participation of the European Union Member States.

3.4.3 Process for establishing annual work programmes and measures to ensure and open and transparent methodology for consulting all constituent entities and relevant stakeholders for the identification of its priorities and the design of its activities

The basis for each Annual Work Programme (AWP) will be the initial multiannual work programme laid out in the Grant Agreement. This will be revised and defined in more detail across the broad annual programming process, which will centre on meetings gathering both the Partnership Consortium partners and external stakeholders.

In particular, both the Research and innovation topics and the specific activities to be yearly tackled by the Partnership will be systematically prioritised according to a set of criteria through a participatory process that will include EU and national policy decision makers, stakeholders as well as the scientific community. For this purpose, during the development of the AWP, specific consultation mechanisms involving both the Partnership Consortium members and the European Commission services will be established.

The Executive Board will be responsible for the operational design and redaction of the AWP which will be subsequently presented, discussed, and agreed by all Partnership members. The ultimate decision-making body for the AWP will be the Governing Board of the Partnership.

Annex I

List of key Initiatives and networks identified:

RESEARCH INFRASTRUCTURES				
ERINHA	European Research Infrastructure on Highly Pathogenic Agents			
ISIDORE	Integrated Services for Infectious Diseases Outbreak Research (ISIDORE): is setting up and offering access to a comprehensive catalogue of integrated and customised research infrastructures' services for epidemics response.			
PHIRI	Population Health Information Research Infrastructure (PHIRI): to enable MS and AS public health bodies to rapidly make available health and care data for COVID-19 research queries and to exchange best practices.			
DURABLE	The DURABLE project will support the HERA laboratory network by providing high-quality scientific information in record time in order to prepare and respond to cross-border health threats.			
EU-HIP	EU-HIP supports countries towards interoperability with HERA's upcoming IT platform, coordinated by SSI			
ECDC Lab network	EVD-LabNet is a multi-disciplinary network of expert laboratories. Its aim is to strengthen Europe's laboratory capacity and capability to respond to emerging, re-emerging and vector-borne viral disease threats			
RESEARCH DATA SHARING				
European COVID-19 Data Platform	Joint effort by the European Commission, EMBL-EBI, the ELIXIR research infrastructure, EU Member States and other partners. The Platform holds over 8,5 million records of diverse data types, including over 4 million viral genomes deposited from 110 countries			
Beyond-COVID - BY COVID	53 organisations (including hospitals) from 19 countries join forces to provide comprehensive open data on SARS-CoV-2 and other infectious diseases across scientific, public health, socio-economic and policy domains			
European Nucleotide Archive (ENA)	The European Nucleotide Archive (ENA) is an open, supported platform for the management, sharing, integration, archiving and dissemination of sequence data			
EUROPEAN CLINICAL TRIAL NI	EUROPEAN CLINICAL TRIAL NETWORKS			
СОМЕСТ	Coordination Mechanism for Clinical Trials and Cohorts. CSA which objective is to enhance Europe's clinical research preparedness and response capacity to infectious disease outbreaks with epidemic potential.			
Trial Coordination Board (TCB)	Ensure complementarity and cooperation across the trials			
CONTAGIO	CSA COhorts Network To be Activated Globally In Outbreaks. consortium of investigators from Europe, North America, Latin America, Asia, and Africa, that aims to create coordination mechanisms to rapidly react to infectious disease (re-)emergence in LMICs			

EU RESPONSE - DisCoVeRy trial	Build a multinational, adaptive European COVID-19 and emerging infectious diseases trial network. Expansion of the DisCoVeRy trial in Europe, to test
(hospitalised patients)	potential treatments for COVID-19
EU RESPONSE - SolidACT trial (hospitalised patients) -	Pan-European platform for pandemic research and preparedness providing a modular trial network enabling European hospitals to participate at the level of commitment that aligns with their capacity.
ECRAID-Prime (project - set up a trial with a primary care patient population)	European Clinical Research Alliance on Infectious Diseases: Primary care adaptive platform trial for pandemics and epidemics
ECRAID-Base (project – set up a trial with a hospitalised and primary care patient population)	Build a "warm-base" European clinical research network for infectious diseases, that has the capacity and capability to function as a platform in hospital care and primary care for a rapid research response in the face of serious infectious disease outbreaks.
ECRIN	European Clinical Research Infrastructure Network, facilitates multinational clinical research, through the provision of advice and services for the set-up and management of investigator or SME led clinical studies in Europe
REMAP-CAP trial (intensive care patients)	A Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia
VACCELERATE	Clinical trials network focusing on vaccine trials; core infrastructure for applied vaccine research with site network (39 countries, 491 sites) and volunteer registry (25 countries, 22 languages, >100,000 volunteers).
COHORTS	
Cohort Coordination Board	Ensure complementarity and cooperation across the cohorts
covicis	Combating SARS-CoV-2 Pandemic: global approach coupling powerful state- of-the-art virologic and immunologic platforms with large genomic surveillance studies and diverse cohorts in EU and Sub-Saharan Africa
EU-CARE	With the support of immuno-virological and artificial intelligence components, the project will take advantage of hospital patients, vaccinated healthcare workers, and schools' cohorts from 11 strategic countries across Europe, Russia, Africa, Asia and Central America to science and society
ORCHESTRA	Three-year international research project aimed at tackling the coronavirus pandemic, led by the University of Verona and involving 26 partners (extending to a wider network of 37 partners) from 15 countries
VERDI	Generate improved evidence on the epidemiology, outcomes, prevention and treatment of variants of SARS-CoV-2 amongst children and pregnant women. It will also improve understanding of the epidemiology and impact of Mpox in children, pregnant women and high-risk group
EU PARTNERSHIPS	
Innovative Medicine Initiative	Improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. Collaboration between universities, research centres, the pharmaceutical and other industries, SME), patient organisations, and medicines regulators

European partnerships on Transforming Health and Care systems A partnership with health and care systems owners/organisers and refunders to boost research in policy, uptake and scale-up of innovation accelerate transformation of national/regional health and care systems		
European Partnership One Health Antimicrobial Resistance (OH AMR)	Fight antimicrobial resistance (AMR)' forming a strong and structured ecosystem with shared evidence, tools and methodologies cutting across sectors	
European Institute of Innovation and Technology (EIT)	Nurturing entrepreneurial talent and supporting new ideas. European initiative that empowers innovators and entrepreneurs to develop world-class solutions to societal challenges and creates growth and skilled jobs	
EU Health Data space	The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities	
ERA4Health	Increase European transnational collaborative research funding by creating a funding body for joint programming in priority areas addressing European public health needs. 32 entities and 27 funding organisations from 21 countries	
European Partnership on Animal Health and Welfare (PAHW)	Structure and support a network of living labs and research infrastructures accelerating the transition towards agroecology throughout Europe. Provide ready-to adopt practices that support farmers in understanding and implementing agroecological practices at the scale needed for positive economic, environmental and social impacts	
European Open Science Cloud (EOSC)	Pan-European project designed to create a virtual environment for sharing and accessing research data across borders and scientific disciplines	
European Partnership on Artificial Intelligence, Data and Robotics	The AI, Data and Robotics (ADR) partnership brings together industry, academia and the European Commission to pursue innovative solutions on a large scale, pooling efforts, resources and investments to generate long-term positive impact	
Global Health EDCTP3 Joint Undertaking	The European and Developing Countries Clinical Trials Partnership (EDCTP) aims is to accelerate the clinical development of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases, including (re-)emerging diseases.	
EU-FUNDED PROJECTS		
СЕРІ	Coalition of Epidemic Preparedness Innovations	
GAVI	The Vaccine alliance (cf. 300 million Euros from the EU)	

CORESMA	COVID-19-Outbreak Response combining E-health, Serolomics, Modelling, Artificial Intelligence and Implementation Research. CORESMA aims to immediately generate the most needed clinical and epidemiological data needed for defining targeted public health measures
ESCAPE	Stakeholders active in infectious disease modelling, public health risk management and science to policy interactions. Improving data accessibility, Scaling up modelling efforts and facilitating science to policy interaction
EU-HIP	Supporting countries towards data interoperability with HERA's IT platform ATHINA.
EU JAMRAI 2	Joint Action on Antimicrobial resistance and health care related infections 2
GARDP	Global Antibiotic Research and Development Partnership
Global Virome Project (GVP)	Stimulate the development of an innovative network of public, private, philanthropic, and civil organizations to detect the majority of our planet's unknown viral threats to human health and food security
HERCOV	SARS-CoV-2-induced activation of pathogenic endogenous retrovirus envelope HERV-W: towards personalized treatment of COVID-19 patients
ID Alert	Infectious Disease decision-support tools and Alert systems to build climate Resilience to emerging health Threats. The project will co-create novel policy-relevant Europe-wide indicators that track past, present, and future climate-induced disease risk across hazard, exposure, and vulnerability domains at the animal, human and environment interface
I-MOVE-COVID	Multidisciplinary European network for research, prevention and control of the COVID-19 Pandemic
EU-WISH	EU-WISH will improve national public health wastewater surveillance capacities to facilitate the integration and complementarity with other surveillance systems with a public health perspective to strengthen preparedness and response to cross border health threats.
Joint Action Integrated	UNITED4Surveillance will contribute to implementation of the new Health
Surveillance	Security framework under the EU regulation on serious cross-border threats to health by Integrating existing and new data sources for more
(UNITED4Surveillance)	comprehensive EU infectious disease surveillance, prevention and control.
Joint Action GHI	European Joint Action to maximise the impact of the EU global health strategy. In the context of the implementation of the new EU Global Health Strategy, better coordination to strengthen this leadership and its visibility is essential to maximize the collective impact of such EU contributions to global health and to shape a new global health order based on our fundamental values.
LEAPS	Integrating Multi-Disciplinary Expertise in a Learning and Adaptive European Pandemic Preparedness System. Demonstrate the feasibility of combining genomic One Health surveillance, with genomic epidemiologic modelling for detailed pathogen understanding and precise public health intervention design. LEAPS will develop protocols and models for accelerated medical countermeasure development, availability and accessibility. Co-created epidemic response scenarios against pathogen X.
MOOD	The MOOD project aims to develop innovative tools and services for the early detection, assessment, and monitoring of current and future

	infectious disease threats across Europe in the context of continuous global,
OneBAT	environmental, and climatic change. One Health approach to understand, predict and prevent viral emergencies from bats
ONE HEALTH EJP	Promoting One Health in Europe through joint actions on foodborne zoonosis, antimicrobial resistance and emerging microbiological hazards
PANDASIA	Pandemic literacy and viral zoonotic spillover risk at the frontline of disease emergence in Southeast Asia to improve pandemic preparedness
PANDEM-2	PANDEM-2 aims to develop new solutions for efficient, EU-wide pandemic management to prepare Europe for future pandemics through innovations in training, building capacity between EU member states responding to pandemics on a cross-border basis.
PCR4ALL	Impact and viability of a novel mass PCR testing method as a pandemic-fighting strategy
PREZODE	Preventing Zoonotic Disease Emergence. 180 partners from 15 countries
RESPOND	Preparedness of health systems to reduce mental health and psychosocial concerns resulting from the COVID-19 pandemic
SHARP JA	Joint Action Strengthened International HeAlth Regulations and Preparedness in the EU
UNDINE	The human genetic and immunological determinants of the clinical manifestations of SARS-CoV-2 infection: Towards personalised medicine
VEO	A Versatile Emerging infectious disease Observatory (VEO) will be created for the generation and distribution of high-quality actionable information for evidence-based early warning, risk assessment and monitoring of emerging infectious diseases (EIDs) and antimicrobial resistance (AMR).
VIROFIGHT	General-purpose virus-neutralizing engulfing shells with modular target- specificity
Foreign Information Manipulation and Interference Toolbox (FIMI)	EU responses to the threat of foreign information manipulation
NETWORKS	
European Patient's Forum	Patient advocacy in Europe providing a cross-disease perspective from a wide patient community to the policy-making process on issues which have a direct impact on patients' lives
European Federation of Pharmaceutical Industries and Associations (EFPIA)	Represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs)
European Global Health Research Institutes Network	Network of leading research institutions in Europe promoting and advocating for Global Health research and innovation

EU network of social scientists	Drawing on our global network of researchers and practitioners, Sonar Global bolsters the contribution of the social sciences in the prevention of and response to infectious diseases and antimicrobial resistance (AMR).
GLOPID-R	Global Coalition of Research Funders in Infectious Diseases with pandemic potential
ISARIC	International Severe Acute Respiratory and emerging Infection Consortium. Global federation of clinical research networks, providing a proficient, coordinated, and agile research response to outbreak-prone infectious diseases.
SSHAP	The Social Science in Humanitarian Action Platform (SSHAP) is a programme of work focusing on the social dimensions of emergency responses.
INTERNATIONAL ORGANISATI	ONS
FIF (Pandemic fund) - World Bank	Financial Intermediary Fund for Pandemic, Prevention, Preparedness and Response ("Pandemic Fund") - 427 M euros from the EC
	The WHO Hub for Pandemic and Epidemic Intelligence; global network to detect and prevent infectious disease threat
	SAGO Scientific Advisory Group on Origins of Novel Pathogens
	ACT Accelerator
World Health Organisation (WHO)	International Pathogen Surveillance Network (IPSN) will provide a platform to connect countries, improving systems for collecting and analysing samples, using these data to drive public health decision-making
	R&D Blueprint: global strategy and preparedness plan that allows the rapid activation of research and development activities during epidemics
	WHO Social Science Working Group
	Independent Panel for Pandemic Preparedness and Response (World Health Assembly Resolution WHA73.1 https://theindependentpanel.org/)
G7	Rapid Response Mechanism

Annex II

$List\ (provisional)\ of\ initiatives\ of\ member\ states\ related\ with\ pandemic\ preparedness$

Country	Name of initiative	Abstract	Reference
AUSTRIA	National pandemic preparedness plan for respiratory diseases	The pandemic plan outlines preparations by the Federal Ministry of Social Affairs, Health, Care, and Consumer Protection (BMSGPK) for respiratory pathogen pandemics like SARS-CoV-2. It details measures for effective management, with flexibility for diverse situations. Regular evaluations ensure alignment with evolving conditions, scientific insights, and legal requirements, guiding BMSGPK actions and interagency coordination.	https://www.sozialministerium.at/dam/fcr:4e2ae8df-e938-4f31-be7a-dd5c6bfe0bf/Pandemieplan%20f%C3%BCr%20respiratorische%20Krankheiten.pdf
	Austrian Climate Research Programme (ACRP)	Climate change, One Health - The ACRP focuses on research on climate change and climate actions, adaptation, mitigation and their mutual interrelation. The intent is to provide scientific background for the implementation of the Austrian strategy for adaptation to climate change, the National Energy and Climate Plan (NEKP) and the Paris Agreement in Austria	https://www.klimafonds.gv.at/call/a crp-2022/; https://www.ffg.at/ACRP_15.Call_i nformationday
	KIRAS Security Research	Pandemic preparedness, data management in health crises as well as waste water surveillance - KIRAS supports national research projects whose results contribute to the security of all members of society. The Austrian security research programme KIRAS implements three mutually complementary instruments. They range from probing actions to cooperative research and innovation projects and R&D support actions.	https://www.kiras.at/en/home#them es:pathGroup=_bedarfstr%C3%A4g er~.wirtschaftgsk~_forschung cate gory-filter:path=default
FINLAND	No specific R&D&I strategy for pandemic preparedness, but national pandemic preparedness plan in preparation	Participates in : Transformation of Health and Care systems, Phiri, BY-COVID, Pandem-2 and Joint Action on Strengthened International Health Regulations and Preparedness in the EU (SHARP JA)	
FRANCE	Acceleration Strategy - Emerging Infectious Diseases SA-MIE	Objectives: -Understand, prevent and control the emergence of new pathogens -Contribute to French preparedness to emerging infectious diseases Challenges: -Reinforce research and innovation potential in the public and private sectors, and industrial transfer -Increase production capacities for countermeasures to secure access (Health products, PPE) -Build French and European preparedness and resilience to sanitary crisis Budget: 750 M€ for 5 years Five axes in continuum -Articulation with EU and international actions, including HERA 1. Interdisciplinary research: mechanisms of emergence, understanding EID, propose and evaluate innovative countermeasures for prevention and medical care 2. Innovation: maturation and transfer, support for public-private partnerships and start-up creation, fostering the development of countermeasures 3. Development of production capacities for countermeasures: securing industrial sectors involved in countermeasures production at French or EU level 4. Preparedness and crisis management: organizational & regulatory aspects 5. Multidisciplinary training: development of transversal competences necessary for research and innovation in EID	https://www.gouvernement.fr/uploa d/media/default/0001/01/2022_03 dossier de presse - france_2030 investir_pour_mieux_repondrea_au x_maladies_emergentes_infectieuse s07.03.2022.pdf

		German strategy for medical and health research. Highlights	
GERMANY	Health Research federal strategy	I. Collaboration across borders in developing solutions to pressing health problems II. Creating synergies III. Linking up current infrastructures at a European or global level IV. Coordinating the joint establishment of new infrastructures	https://www.gesundheitsforschung- bmbf.de/files/Addendum_Rahmenp rogramm_Gesundheitsforschung_b arrierefrei.pdf
GERMANY	Global Health Strategy of the German Federal Government	Presents the German government's political commitment to global health and strategic priorities: V. promote health and disease prevention VI. mitigate the health impacts of climate change VII. strengthen health systems and facilitate the provision of universal health coverage (UHC) without discrimination VIII. safeguard public health protection, including measures to protect against epidemics and pandemics and through continued medical assistance in humanitarian contexts IX. foster global health research and innovation	https://www.bundesgesundheitsmin isterium.de/fileadmin/Dateien/5 Pu blikationen/Gesundheit/Broschuere n/Global_Health_Strategy.pdf
HUNGARY	National Health Security Laboratory	The National Laboratory for Health Security has created a collaborative network of research groups previously operating in isolation in Hungary to carry out scientific research to improve health security. During the ongoing COVID-19 pandemic, the need for in-depth scientific analysis based on reliable data and evidence became clear. The vision of the project is to create a scientific basis for data and analysis-based decision-making in both health and disease control in our country. By bringing together these disciplines, new synergies will be made through innovative surveillance systems, big data methods and mathematical modelling. The National Laboratory for Health Security will bring together and coordinate research groups that have been working in isolation in the country, facilitating networking and creating a collaborative research community both on the national and international levels.	
ITALY	DSB-CNR strategy for pandemic preparedness	The DSB-CNR strategy to face the Covid-19 pandemic and prepare for future ones is divided into three fundamental pillars, further declined in specific project activities: X. Interaction between pathogen and host XI. Strategies for monitoring and managing the epidemics XII. Prevention strategies	https://dsb.cnr.it/pandemics/home- en.html
LUXEMBOURG	Research Luxembourg and Covid-19 Task Force	The COVID-19 Task Force has been set up in order to offer the health system the combined expertise available within the Luxembourg public research sector	https://www.researchluxembourg.or g/en/covid-19-task-force/
	Pandemic Preparedness Agenda	Letter from the minister of Health to the parliament 14 April 2022	https://www.rijksoverheid.nl/docum enten/kamerstukken/2022/04/14/ka merbrief-over-beleidsagenda- pandemische-paraatheid
		Letter from the minister of Health to the parliament 4 November 2022. News message about investment from the Netherlands in CEPI and FIF-PPR:	https://www.rijksoverheid.nl/actuee l/nieuws/2022/11/04/versterking- pandemische-paraatheid-op-koers https://www.rijksoverheid.nl/actuee l/nieuws/2022/10/27/nederland- investeert-in-internationale- paradmische prografied
NETHERLANDS	National action plan strengthening zoonosis policy	Report of expert group zoonosis with recommendations to reduce risks on future zoonotic outbreaks: Zoönosen in het vizier Rapport Rijksoverheid.nl (includes research recommendations)	pandemische-paratheid https://www.rijksoverheid.nl/docum enten/rapporten/2022/07/06/nationa al-actieplan-versterken- zoonosenbeleid https://www.rijksoverheid.nl/docum enten/rapporten/2021/06/01/rapport -expertgroep-zoonosen

			https://www.rijksoverheid.nl/minist
NETHERLANDS	Societal Impact Team work programme: pdf	The Social Impact Team (MIT) advises the cabinet on the social consequences of pandemics and how to deal with them, such as the corona pandemic and corona measures. The MIT provides the government with solicited and unsolicited advice	eries/ministerie-van-sociale-zaken- en- werkgelegenheid/organisatie/comm issies/mit; https://www.rijksoverheid.nl/docum enten/rapporten/20/22/07/06/nationa al-actieplan-versterken- zoonosenbeleid
	Dutch Global Health Strategy 2023-2030	The Dutch Global Health Strategy 2023-2030: "Working together for health worldwide" aims to contribute in a coordinated and targeted way to improving public health around the world, and thus also in the Netherlands	https://www.government.nl/ministri es/ministry-of-health-welfare-and- sport/documents/publications/2022/ 10/21/dutch-global-health-strategy- 2023-2030
	ZonMw, the Netherlands Health Research Organisation	ZonMw runs funding programmes on pandemic preparedness, infectious diseases and COVID-19.	https://publicaties.zonmw.nl/pande mische-paraatheid-themapagina/; https://www.zonmw.nl/nl/onderzoe k- resultaten/gezondheidsbescherming /programmas/programma- detail/kennisprogramma-
	RIVM, , the Netherlands Institute for Public Health and the Environment		pandemische-paraatheid/ https://www.rivm.nl/en/news/new- crisis-response-organisation-at- rivm-to-control-future-pandemics; https://www.rivm.nl/en/who- collaborating-centre-for-infectious- disease-preparedness-and-ihr- monitoring-and-evaluation/fields- of-expertise/research-on-infectious- disease-preparedness-and-ihr-m-e; https://www.rivm.nl/coronavirus- covid-19/omt
	Pandemic and Disaster preparedness Center	PDPC aims to prepare society for future pandemics and disasters, reduce vulnerabilities and risks, build resilience through disaster prevention, preparedness and recovery measures. Convergence of the technical, medical and social sciences is essential for developing	https://convergence.nl/pandemic-disaster- preparedness/#:~:text=PDPC%20ai ms%20to%20preparc%20society% 20for%20future%20pandemics.next %20generation%20of%20approach es%20to%20disasters%20and%20p andemics
	PDCP pandemic Research agenda	the next generation of approaches to disasters and pandemics.	https://convergence.nl/pdpc- publishes-pandemic-research- agenda/
	Research and investment framework of Wageningen University	In the ERRAZE@WUR research and investment framework, researchers from various disciplines work together to help build the scientific foundation needed to prevent future pandemics and to limit their impact.	https://www.wur.nl/en/Research- Results/Research- programmes/Cross-WUR- programmes/ERRAZE-at- WUR.htm
	Norwegian Government's Management of the Coronavirus Pandemic	Two-year-long enquiry into the Norwegian authorities' management of the COVID-19 pandemic.	https://www.regieringen.no/en/doku menter/nou-2022- 5/id2910055/:%20%20
	Long-term COVID-19 strategy to normalise everyday life	Norwegian Government's strategy and emergency preparedness plan for the continued handling of the pandemic.	https://www.regjeringen.no/en/aktue lt/long-term-covid-19-strategy-to- normalise-everyday- life/id2907426/%20:%20
NORWAY	Joint Committee of the Nordic Medical Research Councils	The Joint Committee of the Nordic Medical Research Councils (NOS-M) is a collaborating body for the Nordic research councils that finance medical research. NOS-M aims to coordinate and promote medical research in the Nordic countries, to monitor its progress, and to facilitate information exchange among the countries. The Committee also aims to promote concrete, collaborative Nordic projects in medical research. NOS-M conducts two annual meetings, which rotate between the member countries. Observers from NordForsk, the Nordic Council of Ministers, Science Europe Medical Sciences Committee, Estonia, Latvia and Lithuania are invited to take part in NOS-M meetings and activities. The NOS-M secretariat is hosted by NordForsk.	https:/nos-m.org/publications/;%20
	Norwegian Science Programme on Covid-19	The Norwegian Science Programme on COVID-19 seeks to address critical knowledge gaps for the response to the COVID-19 pandemic. It focuses on: - The virus and the epidemic: How does the virus behave, mutate and spread? How will the epidemic develop?	https://www.fhi.no/en/more/norwegi an-science-programme-on-covid19/

		- Measures and consequences: What are the effects of infection	
	Norwegian Science Programme on Covid-19	control measures on transmission? What are the consequences of the epidemic and the response on health in the population? What are the consequences of the epidemic and the response for society as a whole and the economy? - The health and care services: How can the services best care for patients with covid-19? How can the services avoid negative consequences for other patient groups during the epidemic?	
	National overview of clinical trials		https://www.norcrin.no/en/national- overview-of-covid-19-trials/
NORWAY	Biobank Norway	Biobank Norway represents one of the world's largest existing resources within biobanking covering both consented population-based and disease-specific clinical biobanks. Biobanks in Norway also have access to the unparalleled longitudinal health data making it a unique asset for global research and innovation projects within life sciences, disease prevention and treatment.	https://www.forskningsradet.no/en/
PORTUGAL	Call Research 4 Covid-19 (FCT)	Stimulate national collaborative R&D networks, as well as the reorientation of activity in the R&D units supported by the FCT towards R&D initiatives that meet the needs of the National Health Service (SNS)	https://www.dgs.pt/
	Draft Research and Innovation Strategy for Smart Specialisation of the Slovak Republic 2021-2027	Pandemic preparedness/resilience is briefly addressed under Domain 1 - Innovative industry for the 21st century and Domain 5 – Healthy food and environment.	https://www.mirri.gov.sk/wp- content/uploads/2018/10/Research- and-innovation-strategy-for-smart- specialisation-of-the-Slovak- Republic-2021-2027.pdf
SLOVAKIA	Strategic framework for health care 2013-2030	Strategický rámec starostlivosti o zdravie pre roky 2013 – 2030 (Strategic framework for health care 2013-2030): Increasing the level of pandemic and bio-risk preparedness is mentioned as a priority in the area of public health (part 4.3) without further specification.	https://www.health.gov.sk/?strategi a-v-zdravotnictve
	Act on economic mobilisation	A general act guiding the state's reaction and measures in response to crisis situations, such as the pandemic, as well as preparedness measures to be taken in the state of safety.	
	Pandemic Laboratory Preparedness	Build laboratory capacity to assist the local and national authorities in future pandemics through research (focused on diagnostics, analysis of infection, immunity, and resistance development related to viruses, bacteria and other disease-causing organisms), competence and technology development (focused on sequencing, genetic analysis, immunological methods and management of big data)	https://www.scilifelab.se/capabilitie s/pandemic-laboratory- preparedness/
SWEDEN	10-year national research programme in viruses and pandemics launched in 2021	The research programme is part of the Government's long-term strategy and action plan to counteract and reduce virus outbreaks and pandemics. Its objectives are to contribute new knowledge about viral diseases and the infectious properties and methods of different viruses, how viruses are transferred from animals to humans, the development of new medicines, vaccines and therapies, and how knowledge about equal and gender-equal health can be safeguarded during a pandemic. To build up preparedness ahead of future pandemics, the programme also supports research for knowledge about the economic and social effects of large and long-term societal spread.	https://www.vr.se/english/mandate s/funding-and-promoting- research/viruses-and- pandemics.html